Quality of care, quality of life and complications in surgery

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Chapter 1

Introduction and outline of the thesis

Introduction

Outcome measurement in surgery is increasingly getting attention nowadays. The government, health care insurance companies, and patients demand insight in the performance of health care professionals to assess whether professional standards are met and to make an informed decision about which health care provider to turn to in time of need. Also, health care professionals themselves are interested in outcome measurement, mainly for the purpose of improvement or maintenance of quality of care. Measurement of quality of care is very important. Unfortunately, however, it also poses several difficulties. This introductory chapter gives an overview of the main aspects of quality of care and outcome measurement in surgery and provides an outline of the thesis.

Quality of care and its measurement

Measurement of quality of care has gained importance in recent years, since both the government and the health care consumers in western society demand insight in health care providers' performance. Measurement of quality of care may identify areas of care that need quality improvement and in turn may improve delivered healthcare through feedback of their performance to the providers. Besides, transparency of performance and outcomes is a way of empowering the patient to choose a well performing health care provider. Historically, in surgery the registration and presentation of complications in morbidity and mortality rounds was the major way to assess quality of care, and for most time this was the only way a surgeon's performance was assessed. Obviously, lack of complications will not necessarily mean that good care has been delivered. The first question to be addressed is: what is quality of care?

Quality of care can be defined as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge"[1]. Quality of care usually is assessed through structural measures, process measures and outcome measures[2,3]. Structural measures represent a very broad group of variables that reflect the setting in which care is delivered. Examples are the hospital- or surgeon volume of specific surgical procedures or medical treatment, subspecialty training of health care providers and presence of closed format intensive care units. Studies have shown that the risk of complications in the Intensive care Unit (ICU) is lower with higher nurse-to-bed ratios[4] and that hospital mortality is lower when a system of daily rounds with certified intensivists was employed on the ICU[5]. Many structural measures are related to surgical outcomes while they have the advantage that they are more easily measured than outcome measures. The relationships between structural measures and actual outcome however are incompletely understood and usually focus on volume and mortality. The major disadvantage is that structural measures only imperfectly reflect quality[3]. Process measures refer to the particulars of care that patients actually receive. Examples are the proportion of patients with sepsis that receive antibiotics while in the emergency department, the proportion of patients with myocardial infarction that are discharged with aspirin and β-blockers and the proportion of patients that receive adequate

measures to prevent contrast nephropathy. Many process measures are strongly related to patient outcomes. A major advantage of process measures is the that they are readily actionable: health care providers can change their practice to meet the current standards. Process variables however, may be more difficult to measure and there is a lack of evidence concerning which processes are important for specific patient populations or procedures[3]. Outcome measures more directly assess the outcome of therapy and include mortality, complication rates, length of stay, readmission rates, patient satisfaction, health status, and quality of life[3]. The most important initiative on outcome measurement has been employed by National Veterans Affairs hospitals by way of the National Surgical Quality Improvement Program (NSQIP) which assesses hospital specific morbidity and mortality rates across a wide range of surgical specialties and procedures[6]. Using outcome measures to assess quality has intrinsic validity, since directly measuring the outcome of treatment most accurately represents the quality delivered. Besides, measuring outcome may improve outcome by creating awareness and by the Hawthorne effect (outcomes tend to improve when surgeons know they are being evaluated). The major drawbacks of outcome measures relate to sample size and the relatively large effort it takes to record outcome measures. Since many surgical procedures have low mortality and complication rates, large numbers of patients are required to adequately compare results between health care providers[3].

Outcome measurement: complications

Among the most frequently reported outcome measurement in quality of care assessment in surgery are (30-day) mortality and morbidity. Perioperative mortality is usually defined as death within 30 days, although other definitions may be used[7]. For high risk procedures, mortality may be used as an outcome parameter, however, many procedures have a mortality rate that is far too low to serve as an outcome parameter. For example, in inguinal hernia surgery and cholecystectomy, the risk of mortality is very low and therefore, mortality has no use as an outcome parameter in these procedures. Complications however, can serve this purpose. Morbidity is often described by the terms adverse events, adverse effects, iatrogenic illness or complications[8]. These, unfortunately, are often used interchangeably with no clear definitions given. The negative results of any treatment, broadly referred to as adverse events, can be identified as either complications, sequela, or failures of therapy[9]. According to Clavien et al, complications in surgery all tend to have the following characteristics: (1) they usually occur as the result of a procedure, (2) they are deviations from the ideal course and tend to impair or delay recovery, (3) they induce changes in the management of the patient (diagnostic or therapeutic) (4) they cause morbidity in patients, (5) they occur during the procedure or during the recovery from it[9]. Sequelae are defined as negative effects inherent to the procedure, such as surgical scars or the problematic defecation after rectal excision. The major characteristic feature is that they are a direct result of the operation, due to changes in anatomy or physiology caused by the operation. Failures of surgical therapy occur when the original target of the procedure is not fulfilled in spite of correct execution of the procedure, e.g., when there is irradical resection of tumor in an oncological procedure, such as lumpectomy

for breast carcinoma. Although a sound definition is very important, a complication is often broadly defined as an unexpected event, illness or injury caused by medical intervention (i.e. wound infection after surgery) or disease progression (i.e. diabetic retinopathy). In surgical literature reporting of complications is far from uniform[10]. It is obvious that if adequate registration of complications is to be achieved for meaningful measurement of quality of care, uniform definitions are essential. The Association of Surgeons of the Netherlands (ASN) in their efforts for a nationwide uniform complication registry (LHCR, Landelijke Heelkundige Complicatie Registratie). uses a definition which more specifically applies to surgical practice. It defines a complication as "an unintended and undesirable event or condition following medical treatment, that is harmful for the patient and leads to irreversible damage or necessitates a change in therapeutic policy" [11].

Why should we register complications?

Complications in surgery are an important cause of significant morbidity and mortality[12]. Complications are undesired outcomes and may therefore serve as an indicator of quality (outcome measurement), and may signal possible flaws in the care provided. Therefore, the registration of complications is traditionally performed in surgical wards to evaluate performance and to improve performance if necessary. Besides, complication registries may be used for scientific purposes.

Ways of registering

Several ways are used to assess complications in surgery. Since long time, morbidity and mortality rounds have been the prime occasion where unfavourable outcomes such as complications or death following treatment were discussed. In many teaching hospitals throughout the western world, weekly discussion of complications and mortality with surgical trainees and staff present are a prime requirement. The major drawback of morbidity and mortality rounds is that far less complications are recalled and recorded in comparison with complication registries[13,14].

Retrospective medical chart review was developed by the Harvard Medical Practice Study and has been proven to be valid in identifying adverse events. The methods used have been repeated by several other studies[15-19]. These methods however have several limitations. If the adverse event has not been described in the medical records it cannot be captured and even when medical records contain information on the adverse events, such information could be overlooked by the reviewers. Both mechanisms may lead to underestimation of the incidence of complications.

A more recent development is the use of complication registries. They may be employed on a local (hospital) level, on a regional or national level. Examples of these registries are the NSQIP[6] and the nationwide complication registry of the Dutch Surgical Association (LHCR). Although registries are better at recording complications, they are not perfect: studies have shown that up to 27%-80% may be missing from the registries[20,21] and that complications often are recorded incorrectly[22]. Of course, the adequacy of the registries depends on how well organized they are and the attention and priority given to complication recording during clinical practice. The NSQIP

program was developed by the American College of Surgeons and was created to measure and enhance the care of surgical patients. Recording is done by specifically trained dedicated nurses which may yield higher coverage of complications than less well organized registries.

Classification of complications and consequences of complications

Similar recorded complications do not all have similar consequences. For example, wound infections may be treated with local wound care, antibiotics or even (repeated) surgery. Therefore, when complications are used for assessment of quality of care the severity and consequences of the complication should be taken into account. For example, when two hospitals both have a 10% incidence of anastomotic leak following colon surgery, they seem to be performing equally. However, when in one of the hospitals all patients with an anastomotic leak recover following a single reoperation, while in the other 50% of the patients with an anastomotic leak have one or more reoperations and multiple organ failure and require a lengthy ICU admission, these hospitals obviously are not performing equally. A study has shown that well performing hospitals may not so much differ in their complication rates, but more so in the way they treat the complications and the outcome of this complication treatment. The authors of this study[23] suggested the use of "failure to rescue", defined as death after a complication, as an outcome measure in addition to or instead of complication rates. Hence, it follows that the impact of complications does matter and has been addressed by multiple studies. Complications are related to increased length of hospital stay, repeated surgery, additional medical treatment, legal issues and increased costs[12,24-32]. To use complications to compare quality of surgery, it would be necessary to be able to classify the complications according to their impact, or severity. In 1992 a classification system was developed by Clavien et al., which defined the severity of the complication by the actions necessary to treat the complication[9]. Although the initial system has not been widely used, a revised version has gained popularity[33] and is now commonly used in surgical literature[34]. Efforts have been made to validate the system using both input from caregivers as well as patients[35]. However, at present the system has not been validated by relating the classification's severity grades to validated patient reported outcome measures.

Complications and patient reported outcome measures (PROM)

Although the impact of complications can and should be addressed using objectively measurable variables, such as length of stay, readmissions, repeated surgery and costs, the patients point of view regarding which complications are more severe than others, should also be taken into account. What it actually means for a person to experience these complications, has hardly been subject of investigation: fairly little is known about the effects of complications for the individual patient. One can imagine that experiencing even minor complications may have a large impact on a patient's life, in terms of physical, social and mental wellbeing. The effects of complications on patients' quality of life, health status, depressive feelings and anxiety levels, so far have hardly been studied. The most accepted and most objective way to address this

issue is the use of patient reported outcome measures (PROM). Quality of Life (QoL) and Health Status (HS) are closely related, but different concepts and are among the most frequently reported PROMs in medical research. No fully agreed definition of QoL exists, although the World Health Organization defined it as: "individuals' perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. It is a broad ranging concept affected in a complex way by the persons' physical health, psychological state, level of independence, social relationships and their relationship to salient features of their environment" [36]. Cross-sectional studies evaluating QoL in patients that had undergone colorectal surgery found an association between postoperative complications and decreased long-term QoL[37,38,39]. Health status assesses physical, mental and social functioning, but does not take into account the perception of the individual patient and his or her values and expectations[40]. The two concepts differ in this aspect that QoL primarily assesses how a patient evaluates his physical, mental and social functioning, while HS assesses this very physical, mental and social functioning alone. For example, HS questionnaires may ask "what distance can you walk", whereas QoL of life questionnaires would ask "are you satisfied with the distance you can walk?". The concept of QoL is first and foremost subjective and can only be determined by the individual[40]. Both HS questionnaires and QoL questionnaires, both of which have many variants, are often used in medical literature. Other psychological factors that can be measured using questionnaires might be influenced by complications are anxiety and depressive symptoms. Anxiety and depressive symptoms have been less well been documented. A study has been performed that showed increased prevalence of anxiety one year after colorectal surgery[41] and another study showed increased depressive and anxiety symptoms in case of complications after mastectomy for breast cancer[42]. Although no evidence exists, the hypothesis that postoperative complications after colorectal surgery increase patients levels of anxiety and depressive symptoms in the postoperative period seems likely. Since these patients may benefit from psychological counselling, it is important to assess whether anxiety levels and depressive symptoms are increased in patients experiencing complications after colorectal surgery.

Outline of the thesis

This thesis constitutes three parts. The first part concerns the impact of complications on objectively measurable variables, whereas the second part relates to the impact of complications on patient reported outcome measures. The third part describes two studies in which the complication registry has been used to investigate the influence of process variables on outcome. *Chapter 2* describes the severity of complications as well as the impact that various complications have in a large patient cohort from our database. Similarly registered complications (for example wound infections) may vary with respect to their severity and their consequences. *Chapter 3* investigates the severity and impact of a subgroup of entries in our complication database: medical errors. *Chapter 4* addresses the impact of complications in colorectal surgery on quality of life and the relationship between the severity grade of complications and QoL. *Chapter 5* evaluates the impact of complications on health status, anxiety and depressive symptoms following colorectal surgery. The last part illustrates the use of the complication registry for outcome research to answer two clinical questions. *Chapter 6* answers the question whether operative treatment of pertrochanteric fractures outside working hours is as safe as operative treatment during daytime hours. The second question addressed in *Chapter 7* concerns whether appendectomy by residents alone is as safe as appendectomy by directly supervised residents or surgeons as the primary operating surgeon. A summary and general discussion on the study results as well as the implications for clinical care and future research are provided in *Chapter 8*.

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Chapter 2

The variable impact of complications in general surgery: a prospective cohort study

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Abstract

Introduction

Registering complications is important in surgery, since complications serve as outcome measures and indicators of quality of care. Few studies have addressed the variation in severity and consequences of complications. We hypothesized that complications show much variation in consequences and severity.

Methods

A prospective observational cohort study was conducted to evaluate consequences and severity of complications in surgical practice. All recorded complications of patients admitted to our hospital between June 1st 2005 and December 31st 2007 were prospectively recorded in an electronic database. Complications were classified according to the system of the Trauma Registry of the American College of Surgeons (TRACS). Severity of complications was graded according to the system proposed by Clavien and the consequences of each complication were registered.

Results

During the study period 3418 complications were recorded. Consequences and severity were recorded in 89% of complications. Of 3026 complications, 987 (33%) were grade I, 781 (26%) were grade IIa, 1020 (34%) were grade IIb, 150 (5%) were grade III, and 88 (3%) were grade IV. The consequences and severity of identically registered complications showed a large degree of variation, best illustrated by wound infections, which were grade I in 50%, grade IIa in 22%, grade IIb in 28% and grade III and IV in 0.3% of cases.

Conclusion

On the basis of these results we suggest that the severity of complications should be routinely presented when reporting complications in clinical practice and surgical research papers to adequately compare quality of care and results of clinical trials.

Introduction

Complications in surgery are an important cause of morbidity and mortality and may result in increased length of hospital stay, repeated surgery, additional medical treatment, as well as legal issues and increased costs[1-5]. Apart from mortality, complications are among the most frequently measured and reported endpoints to evaluate surgical treatment[6]. They are used as an indicator of quality as a complication registry and its continuous evaluation can identify possible flaws in the process of care. Although good efforts are currently made to improve quality of care by a uniform registration of adverse events and mortality[7], unfortunately, in many countries comparison of outcomes among health care providers is hampered by lack of clear definitions of complications[8,9]. Besides this, when comparing outcomes of treatment, the severity of complications is usually not taken into account. Differences in recorded severity of complications however, may reveal differences in quality of care and subsequently provide opportunities for improving quality of care.

In 1992 a classification system was developed by Clavien et al., which defined the severity of the complication by the actions necessary to treat the complication[10]. The system initially has not been widely used, although a modified version has significantly gained in popularity after it has been validated in a large cohort of patients and has been shown to have good reproducibility among surgeons[11]. In surgical literature only limited information on the consequences and severity of complications is found. We hypothesized that the impact of comparable complications is highly variable. The aim of our study was to prospectively evaluate the severity and consequences of all complications arising in a general surgical practice, and to evaluate whether identically recorded complications have predictable and consistent severity grades. From these results, we can infer whether crude complication rates can serve as indicators of quality of care and outcome measures in scientific research, or that gradation of complications is obligatory for adequate comparison of outcomes.

Methods and definition of complications

All recorded complications of patients admitted to our hospital between June 1st 2005 and December 31st 2007 were analysed.
The registration methods and classifying systems used have been previously described in detail[12]. Negative outcomes were differentiated into complications, sequalae and failure to cure[10]. Traditionally, in our hospital the definition of the Association of Surgeons of the Netherlands (ASN) is used: "A complication is any state or event, unfavourable to the patient's health, that arose during admission or 30 days after discharge that either causes unintentional injury or requires additional treatment."[13]. Over the years, this definition has been broadened. Complications that arise more than 30 days after discharge are also recorded and measurable negative effects or additional treatment are no longer absolute requirements. Thus, undesirable events without directly noticeable negative effects on the patients' health or without need for additional treatment are recorded as well, regardless of the actual effect for the patient. These events are recorded as provider related complications and constitute up to 4% of events in our registry[13].
Complications were classified according to the system of the Trauma Registry of the American College of Surgeons (TRACS). The system does not provide information about severity of the complication. The Trauma Registry of the American College system was originally developed as a complication list to record the morbidity in trauma patient populations[14]. The list explicitly defines complications and uses four-digit-codes. Although this list was developed for the trauma population, its design is broad and encompasses complications applicable to general surgery.
When an event occurs, it is immediately registered in the patients electronic medical record by the physician who identified the event. The complication, including its severity grade and consequences, is recorded in an electronic medical file within the patients record, which is especially designed for registering complications. This file is operational on all computers throughout the hospital and the outpatient clinic, which makes recording easy. All complications recorded for admitted patients as well as patients at the emergency department and the outpatient clinic are automatically presented at the daily surgical conference and discussed by the entire surgical staff, before they are definitively recorded in the database. The software used for the electronic medical record is a Microsoft-Access application with an Oracle-database as back-end, which was developed in our hospital. For the purpose of this study, the severity of the complication was graded according to the system proposed in 1992 by Clavien et al[10]. In this system the severity of the complication is defined by its consequences. Thus, the most severe complications are those resulting in death (grade IV). The severity of complications not resulting in death is defined by the morbidity it inflicts on the patient. Morbidity may vary from no or very minor consequences (grade I), pharmacological treatment (grade IIa), additional diagnostic or therapeutic procedures (grade IIb), or lasting disability (grade III). The classification system was designed for classifying severity of complications after cholecystectomy, but is applicable to all surgical procedures. Besides this, the immediate consequences of each complication were

scored in a qualitative way by the recording physician. The following consequences could be scored: readmission, complication expected to prolong hospital stay, transfer to another department or hospital, surgical reintervention, pharmacological treatment, radiological drainage, opening of the wound for drainage, intubation and artificial respiration, delay of surgery, death, other, or a combination of these. A free-text description of the consequences of the complication was also recorded. Since the registration and coding of complications is known to be frequently incomplete and inconsistent[12], all complications, consequences of complications and Clavien severity grades were reviewed and the coding checked against the recorded free-text description of the complication. If incorrectly coded, the registered entries were corrected using the TRACS manual or the instructions in Clavien's paper[10]. Documented entries which were no complications, but failures of therapy, negative effects of the primary disease or sequalae were identified and excluded from analysis.
Statistical analysis calculating frequencies and cross-tabulations was performed using the Statistical Package for the Social Sciences (SPSS) version 16.0.

Results

In the period a total of 12121 patients were admitted of whom 8384 (69%) underwent a total of 15058 surgical procedures. In operated patients, 20%(1639/8384) of all patients had one or more complications registered, whereas in non-operatively treated patients, this was the case in 11% (394/3737) of patients. We documented a total of 3418 complications in 2033 patients (17% of all admitted patients). Figure 1 shows the flow chart of the study. In 368 complications, no consequences or severity grades were recorded and were excluded from the analysis. The consequences of 3050 (89%) of a total of 3418 complications were adequately registered. After reviewing the nature and description of all documented complications, 24/3418 (0.7%) events were actually either new pathology, negative effects of the primary disease, or sequalae and were also excluded from analysis.
The various types of procedures performed and their respective complication rates are outlined in table 1. In admitted patients that were not operated, in 465/552 (84%) consequences of the complication were recorded.

Figure 1. *Flow chart of the study*

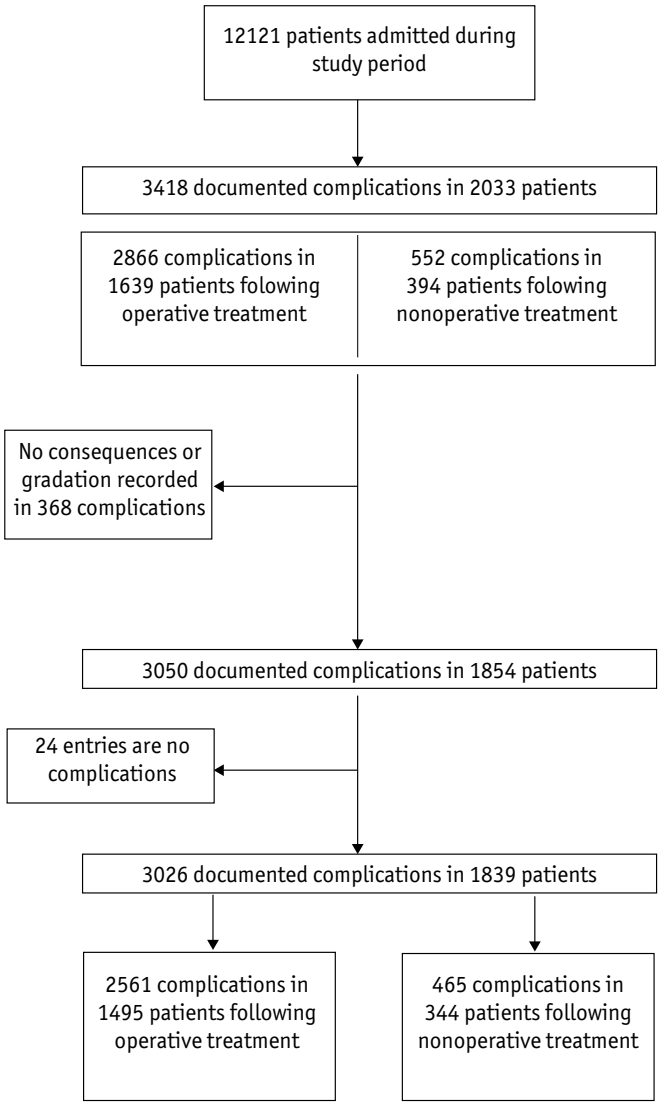

Table 1. *Complications in relation to type of surgery*

	I **Patients**	II **Operative procedures**	III **Patients with ≥1 complication registered**	IV **compli-cation rate (III / II)**	V **compli-cations register-ed**	VI **Patients with ≥1 complications with severity rades and consequences registered**	VII **Complications with severity grade and consequences registered**	
	n patients	n procedures	n patients	%	n compl	n patients	n compl	% (VII / V)
Vascular Surgery	989	2188	280	13	515	243	444	86
Gastro-intestinal Surgery	2212	4439	630	14	1252	583	1147	92
Trauma Surgery	1093	2101	231	11	347	215	312	90
Breast Surgery	541	1126	122	11	151	104	124	82
Thoracic Surgery	101	330	50	15	93	49	85	91
General Surgery	3294	4674	306	7	481	284	428	89
Head and Neck Surgery	154	200	20	10	27	17	21	78
Total	8384	15058	1639	11	2866	1495	2561	89

Compl = complications

Table 2. *Severity of complications in relation to type of surgery*

Type of procedure	Patients	Complications - gradation according to Clavien et al.										
		I		IIa		IIb		III		IV		
	n patients	n com	%	n com	%	n com	%	n com	%	n com	%	Total
No operative procedure	3737	248	53	99	21	95	20	14	3	9	2	465
Vascular surgery	989	107	24	143	32	135	30	30	7	29	7	444
Gastro-intestinal Surgery	2212	324	28	344	30	387	34	59	5	33	3	1147
Trauma Surgery	1093	105	34	61	20	117	38	24	8	5	2	312
Breast Surgery	541	25	20	19	15	80	65	0	0	0	0	124
Thoracic Surgery	101	25	29	23	27	37	44	0	0	0	0	85
General Surgery	3294	148	35	83	19	162	38	23	5	12	3	428
Head and Neck Surgery	154	5	24	9	43	7	33	0	0	0	0	21
Total	12121	987	33	781	26	1020	34	150	5	88	3	3026

Com= complications

Table 2 illustrates the severity of complications following various types of surgery. Of all complications, 92% had no lasting effects for the patient (grade I, IIa and IIb), although one third of these required major additional interventions. The most serious complications (grade III and grade IV) occurred after vascular surgery (N=30/989, 3% for grade III and N=29/989, 2,9% for grade IV complications), gastrointestinal surgery (N=59/2212, 2,7% for grade III and N= 33/2212, 1,5% for grade IV complications) and trauma surgery (N=24/1093 2,2% for grade III and N=5/1093, 0,5% for grade IV complications).

Table 3 shows the consequences of complications, with respect to different complication grades. It shows, for example, that 22% of all readmissions were due to grade I complications, 17% were because of grade IIa complications and 60% of readmissions were necessary to treat grade IIb complications. The category "other" encompassed potential damage to the patient, delay of adequate treatment and additional minor procedures such as new plaster casts, new intravenous (i.v.) lines, new nasogastric tubes or urinary catheters, among others. The table illustrates,

Table 3. *Consequences of complications in relation to severity grade*

	Gradation according to Clavien et al.										
Recorded consequences	**I** (n=987)		**IIa** (n=781)		**IIb** (n=1020)		**III** (n=150)		**IV** (n=88)		**total**
	n	**%**	***n***	**%**	***n***	**%**	***n***	**%**	***n***	**%**	**n**
Readmission	72	22	55	17	198	60	6	2	1	0,3	332
Reoperation	21 *	2	0	0	823	93	28	3	13	1	885
Radiological drain	0	0	0	0	84	100	0	0	0	0	84
Opening of wound abscess	217	89	26	11	0	0	0	0	0	0	243
Expected increased length of stay	129	20	175	27	284	43	49	8	16	2	653
Pharmacological treatment	58	6	754	74	138	14	46	5	21	2	1017
Intubation/mechanical ventilation	0	0	0	0	83	85	7	7	8	8	98
Transfer to another department	14	8	75	43	49	28	25	14	10	6	173
Delay of operation	168	85	15	8	8	4	4	2	2	1	197
Other	506	88	24	4	34	6	7	1	2	0,3	573

**bedside procedure; The percentages reported with each severity grade represent the proportion of the total number for this recorded consequence.*

that even grade I complications have a broad spectrum of consequences, including readmissions, increased length of stay, pharmacological treatment (although these only include anti-emetics, antipyretics, analgesics antidiarrheal drugs and drugs required for urinary retention)[10] and transfers to other departments. It also shows that although in grade III and IV complications disability and death are the ultimate consequences, complications often had many other consequences such as reoperations, medical treatment and artificial ventilation

Table 4 shows the top-five most frequent reasons for readmission for every severity grade. In grade I most readmissions were due to complications recorded by TRACS codes that denominate provider errors. The complications recorded by TRACS code 9003 “delay to operating room” were all cases in which an elective operation was cancelled either due to low operating room or ICU capacity or the patient’s condition. The operation was then rescheduled and the patient readmitted at another day. The complications recorded by TRACS code 9008 “error in judgement” encompassed cases in which patients were admitted as a consequence of inadequate analgesic prescription, an erroneous therapeutic regimen or an erroneous diagnostic work-up. The complications recorded by TRACS code 9004 “delay in MD response” includes a case in which a patient was admitted for an Endovascular Aneurysm Repair (EVAR) procedure, but the EVAR device was not present. The operating surgeon, although aware of this fact, had failed to cancel the operation. The other two cases are severe hypertension in a patient that was known to the operating surgeon who did not take

Table 4. *registered complications requiring readmission*

Grade I (n=72)			**Grade IIa (n=55)**			**Grade IIb (n=198)**		
TRACS description	n	%	TRACS description	n	%	TRACS description	n	%
Delay to operating room	26	36	Wound infection	20	36	Wound infection	60	30
Wound infection	19	26	Postoperative hemorrhage	4	7	Error in technique	27	14
Error in judgement	5	7	Pneumonia	3	5	Intra-abdominal abscess	19	10
Delay in MD response	3	4	Pulmonary Embolus	3	5	Postoperative hemorrhage	15	8
Error in diagnosis	3	4	Urinary tract infection	3	5	Loss of reduction/fixation	9	5
Grade III (n=6)			**Grade IV(n=1)**					
TRACS description	n	%	TRACS description	n	%			
Myocardial infarction	1	17	Septicaemia	1	100			
Bowel inhury-iatrogenic	1	17						
Dehiscence-evisceration	1	17						
Necrotizing fasciitis	1	17						
Other infection	1	17						

appropriate measures and a case in which no operating surgeon was available while it was already clear that this would be the case when the operation was planned. The complications recorded by TRACS code 9007 ”error in diagnosis” are three cases in which an incorrect diagnosis (peroperatively in 2 cases) lead to a readmission. Finally, in grade IIb complications, 27 surgical technical errors, as documented by TRACS code 9009 “error in technique” caused the patient to be readmitted, these included incorrectly placed vascular access ports, incorrectly performed osteosynthesis and insufficiently drained abscesses.

Table 5 shows the severity the most commonly encountered complications in surgery. It illustrates that similar complications vary widely in consequences and thus, severity grade. This is best illustrated by wound infections, which were grade I in 50% of cases, grade IIa in 22%, and grade IIb in 28%, grade III in 1 patient (0.3%) and grade IV in another patient. Pneumonia could be treated medically in 155 (90%) cases but it required intubation and ventilation (grade IIb) in 5% of patients suffering from pneumonia, and caused death in 5 (3%) cases. Postoperative haemorrhage required reoperation (grade IIb) in 72%, but was treated conservatively in 24% of cases and caused death in 2.2% of patients with this complication. Most other complications also show a fairly wide spectrum of severity.

Table 5. *Severity grades of the most frequently occurring complications according to Clavien et al.*

		SEVERITY GRADE											
TRACS	DESCRIPTION	I		IIa		IIb		III		IV		Total (n=3026)	
		n	%	n	%	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
5509	Wound infection	197	50	85	22	111	28	1	0,3	1	0,3	395	13,1
8508	Post-operative hemorrhage	55	24	5	2	165	72	0	0,0	5	2,2	230	7,6
3008	Pneumonia	5	3	155	90	8	5	0	0,0	5	2,9	173	5,7
5507	Septicemia	5	4	78	69	18	16	1	0,9	11	9,7	113	3,7
6003	Urinary tract infection	3	3	104	96	1	1	0	0,0	0	0,0	108	3,6
4003	Abdominal wall dehiscence/evisceration	11	11	2	2	51	51	35	35,0	1	1,0	100	3,3
5503	Intra-abdominal abscess	4	4	3	3	82	91	0	0,0	1	1,1	90	3,0
3501	Cardiac Arrhythmia	11	18	47	77	3	5	0	0,0	0	0,0	61	2,0
7507	Arterial thrombosis	5	8	6	10	40	67	6	10,0	3	5,0	60	2,0
3505	Myocardial infarction	1	2	26	44	0	0	25	42,4	7	11,9	59	1,9
4001	Bowel anastomotic leak	3	6	1	2	43	84	2	3,9	2	3,9	51	1,7
8502	Drug related	19	39	28	57	1	2	0	0,0	1	2,0	49	1,6
3015	Respiratory failure	1	3	3	8	34	85	0	0,0	2	5,0	40	1,3
3504	Congestive heart failure	0	0	28	78	3	8	5	13,9	0	0,0	36	1,2
5504	Line infection	7	20	24	69	3	9	0	0,0	1	2,9	35	1,2
6506	Loss of reduction/ fixation	0	0	0	0	29	85	5	14,7	0	0,0	34	1,1
3009	Pneumo-thorax	2	9	0	0	20	91	0	0,0	0	0,0	22	0,7
6509	Orthopaedic wound infection	1	5	7	35	10	50	1	5,0	1	5,0	20	0,7
4008	Ileus	1	5	5	26	13	68	0	0,0	0	0,0	19	0,6
7011	Stroke/cva	0	0	0	0	0	0	13	72,2	5	27,8	18	0,6
3014	Pulmonary embolus	0	0	9	53	3	18	0	0,0	5	29,4	17	0,6

Discussion

This study shows that severity grades of complications are highly variable, although they are registered by identical descriptions and codes. Therefore, complication rates are of limited value without specifying severity grades. Furthermore, this study shows that although severity grading of complications does tell a lot about the consequences of complications for our patients, it certainly does not tell it all since for example many grade IIb complications also have consequences other than reinterventions, such as pharmacological treatment, intubation and mechanical ventilation, readmissions and transfers to other departments. Interestingly, many grade I complications were also shown to have consequences such as readmission, bedside procedures or transfer to another department, which obviously are associated with discomfort for the patient. The variability of the consequences of complications presumably is depending on the nature of the complication, patient factors, individual doctors' decisions and the quality of care provided to counteract the effects of the complication. In fact, it recently has been shown that hospitals that have high mortality rates, have similar overall complication rates and similar incidence of major complications compared to hospitals with lowest mortality rates. The difference in mortality is probably the result of the way the complication is managed[15]. The fact that severity and consequences of complications are variable, has important implications for daily clinical practice and for evaluating quality of care. Among the best examples of this variability are wound infections, which in surgical literature are usually presented as a single entity[9], at best sometimes distinguishing between deep and superficial wound infections[16]. The results of our study however, show that the severity and consequences of wound infections are highly variable. Half of all wound infections could be treated by bedside procedures, 22% were treated with antibiotics, but up to 28% required operative treatment. The risk of death from a wound infection in our study was extremely small. Wound infections with major consequences on the patient's health may outline a group of more serious complications, a patient category in worse health or worse quality of the care provided to treat the complication. Other complications that had a wide variation in consequences are postoperative hemorrhage, septicaemia, abdominal wall dehiscence, cardiac arrhythmias, myocardial infarction and pulmonary embolus. On the other side of the spectrum were complications that tended to have fairly consistent consequences. Among these were anastomotic leak, which almost always needed operative treatment and urinary tract infection that could almost exclusively be managed pharmacologically.

In recent years, providing patients with information about the intended treatment has received more and more attention. Information sources are more widely available to patients than ever before and patients expect to be properly informed about a treatment and its associated risk. Although medical professionals are highly committed to patient education, they generally tend to underestimate the patients' desire to receive extensive information prior to surgical procedures[17]. Complications are now generally discussed with our patients, but the consequences of complications usually are not discussed in detail. The results of our study may be used to more thoroughly inform patients about

the possible impact of complications.
Assessing the quality of care has become increasingly important to providers, the government and patients with focus on developing performance indicators for measuring outcome[18]. One of the best examples of programs to improve quality of care is the National Surgical Quality Improvement Program by the American College of Surgeons[7]. In surgery complications are generally accepted and used as outcome indicators to compare quality of care. Public opinion and leading medical opinion traditionally focussed on crude mortality and general complication rates, sometimes distinguishing between minor and major complications, without properly defining major and minor complications[8,9,12]. Up to the present day, the lack of a uniformly adopted system for classifying severity of complications has hampered comparability of the events reported in surgical literature, although the Clavien-Dindo system is reported with increasing frequency in surgical literature[11]. The results of our study signify the need for a uniform grading system for complications, especially if these are used as outcome measures. In our opinion, the modified system proposed by Clavien et al.[11] is a serious candidate to become (if it not at present already is) the uniform manner of grading the severity of a complication. It has been used in liver surgery, pancreatic surgery and laparoscopic urologic procedures[19-22]. Compared to the original system, the theoretical framework of the new classification remained the same, but the authors added more subclassifications, including ICU stay and differentiation between procedures under local and general anesthesia as well as differentiation between single- and multiple organ failure. Recently, yet another modification of the system was proposed, named the Accordion Severity Grading system[23]. This system has similarities to both the 1992 Clavien classification system and the Clavien-Dindo system that was presented in 2004. Although these new classification systems may have advantages over the original system, in our study we elected to use the original classification system, since at the time of designing our present study in our hospital we had no experience with the revised (Clavien-Dindo) classification system and extensive support in the literature was lacking at the time. Although some classification systems may have advantages over other systems, it is far more important that a single classification system is used throughout surgical literature to facilitate the comparison of outcomes in surgical research or in clinical practice. The extensive efforts that have been made to validate the Clavien-Dindo system[11,24] as well as the vast number of authors using the this system[24], may well favour this system as the most appropriate international standard for reporting complications.
The Clavien system and it's modifications are valuable tools in complication registries and outcomes research, however, there are also some drawbacks. Disadvantages of both the original and revised systems proposed by Clavien et al. are that they define severity of complications solely from the doctors' point of view and that the duration of the effect of the complication is not taken into account. For example, a reoperation for anastomotic leak is classified identically to a reoperation for postoperative hemorrhage in mastectomy. Almost every surgeon will agree that the former is a more severe complication, with far more devastating and longer lasting impact. Besides, whether a complication necessitating a single reoperation is more severe than a

complication requiring prolonged medical treatment is probably not up to the doctor to decide. Obviously, defining the severity of complications at some point should take into account the patients point of view. Recently, an effort was made to correlate the Clavien-Dindo classification to the perception of the severity of the complication of patients and nurses[24] by using written clinical scenarios, in which it was shown that patients perceive grade III and IV complications of the system as more severe than doctors and nurses. Although at present, this is the only evidence available relating the severity of complications and our patients' perception, it would be better to relate the severity of complications to validated psychological constructs such as quality of life, health status, anxiety and depression. At present however, to our knowledge there are no studies investigating the effect of surgical complications on these psychological phenomena. At the moment a prospective study is conducted in our hospital that is specifically designed to evaluate the psychological impact of complications following gastroenterological surgery.

To our opinion, the results of the present study are both valid and valuable, although there are some limitations. It is a well-known problem that complications tend to be subject to underreporting, which may also be the case in our hospital. Underreporting of complications most frequently occurs when complications are non-severe and not prospectively recorded[25]. Prospective registration has shown to be far superior to morbidity and mortality rounds and suggested as a standard by different authors[25,26]. In our hospital, such a registry has existed for many years with a strong focus on quality improvement. A previous study by our group has shown a clear learning curve with increasing numbers of recorded complications over the years, more likely reflecting better registration than higher complication rates. A change in attitude, definition of complications and real time registry had a severe influence on the incidence of complications then[27]. Although in our registry, in patients undergoing laparoscopic cholecystectomy 90% of complications were adequately registered[13], some underreporting of complications probably is inevitable. If underreporting is present however, it will still not render the conclusions from our study invalid, since the variation in gradation of complications will be little different when registration is complete.

Conclusion

This study illustrates the applicability and usefulness of recording the severity and consequences of complications, and provides insight in the severity and consequences of complications in a general surgical practice. It shows that severity grades within complications are highly variable. There is a need for a universal system for grading severity of complications, to compare quality of care between different health-care providers. Further studies are needed to investigate the effect of complications on patients quality of life and health status. These results must then be used to validate and, if necessary, modify the systems used to grade the severity of complications. Finally, we suggest that registering and recording of the severity complications should become standard practice when reporting complications in clinical practice and surgical literature to compare quality of care and results of clinical trials.

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Chapter 3

Incidence, nature and impact of error in surgery

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Abstract

Introduction

Adverse events occur in 3.8 to17 per cent of hospital admissions. The purpose of this study was to analyze the incidence of medical errors and assess the feasibility of an error registry for quality improvement programs.

Methods

Errors were prospectively recorded in a complication registry between June 1st 2005 and December 31st 2007. Events were coded according to the Trauma Registry of the American College of Surgeons (TRACS), the nature of events was recorded and the severity graded using the 1992 Clavien system. Recorded events were discussed by the medical staff on a daily basis and if by consensus judged to be errors, they were saved to the registry database.

Results

During the study period, 12121 patients were admitted to the surgical ward, 2033 patients (16.8 per cent) had a complication and 735 patients (6.1 per cent) had one or more errors documented in the registry. Of 873 recorded errors, 607 (69.5 per cent) had little or no consequences (Clavien grade I), and 220 errors (25.2 per cent) required therapeutic interventions (Clavien grade IIa and IIb). Errors with permanent injury (Clavien grade III) occurred in 41cases (4.7 per cent) and death of the patient (Clavien grade IV) in five instances (0.6 per cent).

Conclusion

This study shows that errors are common in surgery and that near misses are more frequent than errors with serious consequences. It is hypothesized that registration of near misses might prevent errors with serious consequences and thus improve quality of care.

Introduction

Patient safety and medical error are increasingly getting attention in clinical practice and research. Adverse events account for significant morbidity and mortality and are defined as an unintended injury or complication resulting in prolonged hospital stay, disability at the time of discharge or death and caused by healthcare management rather than by the patients' underlying disease process[1,2,3,4]. Failures to follow accepted practice at the individual or system level are defined by some authors as preventable adverse events[2]. The results of the Harvard medical practice study showed that almost half of all adverse events are preventable[5] and these results have been reproduced in several countries[6,7,8]. Adverse events are estimated to occur in approximately 3.8 to 17 per cent of all hospital admissions and of these events between 37 and 51 per cent are preventable[9]. Approximately seven per cent of events cause permanent disability and another seven per cent cause death[9]. Adverse events may be the result of medical error, although errors do not always result in injury for the patient. If an event could, but did not have adverse consequences for the patient, it is common to speak of a near miss[2]. The common cause hypothesis states that near misses have similar causal pathways as adverse events and is an underlying assumption of many injury prevention programs[10]. The hypothesis has been supported by several reports, that have used data registration of near misses as well as adverse events for injury prevention programs[10,11]. The prospective registration of medical errors, including near misses, provides an opportunity for quality improvement[12] since they may allow identification of causal factors which may lower the risk of major consequences for patients. This study provides an analysis of the incidence, nature, severity and consequences of documented medical errors.

Methods

Definitions

A complication was defined according to the definition of the Association of Surgeons of the Netherlands (ASN) as "a condition or an event, unfavorable to the patient's health, causing irreversible damage or requiring a change in therapeutic policy"[13]. Medical error was defined as an act of omission or commission in planning or execution that contributes or could contribute to an unintended result[2]. These definitions were accepted by the entire surgical staff and were used when documenting errors and complications.

Registration methods

The methods for registration and classification have been described in detail elsewhere[14]. In short, complications and medical errors are prospectively recorded in the hospital's complication registry, which forms an integral part of the electronic medical patient file. All errors that are identified either in the wards or in the outpatient clinic regardless of patient outcome, are recorded. Thus, true complications as well as errors with consequences for the patient and near misses can be analyzed. All recorded entries in the complication registry in admitted patients, either occurring during admission or during follow up at the outpatient clinic, between June 1st 2005 and December 31st 2007, were analyzed.

The hospital where this study was conducted is a secondary referral hospital and a level 1 trauma center, with a capacity of 673 beds. The surgical department consists of 12 surgical residents and 12 consultant surgeons. Each event was recorded in the complication database of the electronic patient record at the time of occurrence by one of the physicians of the surgical team. The database is accessible through the electronic patient record on all computers throughout the hospital and the outpatient clinic. All events recorded for admitted patients as well as patients at the emergency department and at the outpatient clinic are presented and discussed at the daily surgical conference before they are definitively saved in the database. Only if an event is by consensus judged to be due to substandard care it is recorded as an error in the complication registry. The software used for the electronic medical record is a Microsoft-Access application with an Oracle-database as back-end, which was developed by the hospital. All entries in the complication registry were classified according to the system of the Trauma Registry of the American College of Surgeons (TRACS). The TRACS system was originally developed as a complication list to record the morbidity in trauma patient populations[15]. The list explicitly defines complications and uses four-digit-codes. Although developed for a trauma population, the design of TRACS is applicable to general surgery. An advantage of the system is that it allows the registration of medical errors by specific codes[16,17]. In addition to entries that were prospectively recorded as errors, all other registered complications were retrospectively reviewed to screen for miscoded errors. If the recorded free text description of the entry clearly stated an error, it was recoded as a medical error as defined by the above mentioned definition.

The severity of complications and errors is graded according to the system proposed

by Clavien et al[18]. This system was originally designed to classify the severity of complications after cholecystectomy, but is applicable to all surgical procedures. The severity of a complication is defined by its consequences. Thus, the most severe complications are those resulting in death (grade IV). The severity of complications not resulting in death is defined by the inflicted patient morbidity. Morbidity varies from no or very minor consequences (grade I), pharmacological treatment (grade IIa), additional diagnostic or therapeutic procedures (grade IIb), or lasting disability (grade III). At present, the 1992 system has been modified to a uniformly applicable system, that is currently used throughout the world[19]. When the present study was designed late 2004, however, the 1992 Clavien classification was used in the hospital and is therefore referred to in the present report. A free-text description of the consequences of the complication is also recorded. Since the registration and coding of complications is known to be sometimes incomplete and inconsistent[14], all complications, consequences of complications and Clavien severity grades were reviewed and the coding checked against the recorded free-text description of the event by two of the authors. In a previous study the inter-rater agreement between these authors was found to be 0.695[20], which is considered a substantial agreement[21]. If incorrectly coded, the registered entries were corrected using the TRACS manual or the instructions in the original Clavien paper[18]. The total number of procedures during the study period was drawn from the operating room database. In this database each procedure that is performed during one operative session counts as one. For example, if a laparoscopic appendectomy is converted to open appendectomy, both a laparoscopy and an open appendectomy are registered in the database.
Statistical analysis calculating frequencies and cross-tabulations was performed using the Statistical Package for the Social Sciences (SPSS) version 16.0.

Results

During the study period 12121 patients were admitted to the surgical ward, of which 8032 cases (66.3 per cent) were elective and 4089 cases (33.7 per cent) were acute admissions. In 8384 patients (69.1 per cent) a total of 15058 surgical procedures were performed. In operated patients, 1639 (19.5 per cent) had one or more events (both complications and errors) registered, whereas in 3737 non-operatively treated patients, 394 cases (10.5 per cent), had one or more events registered. Nine hundred and forty errors were documented in 788 patients. Sixty-seven errors were excluded from analysis since they were documented prior to the first admission and related to previous admissions or previous treatments. Of 12121 admitted patients, 735 (6.1 per cent) had 873 errors registered.
Errors and complications in relation to the type of surgery are shown in table 1. The incidence of error was highest in thoracic surgery, vascular surgery and trauma surgery, with errors in 10 patients (9.9 per cent), 91 patients (9.2 per cent) and 95 patients (8.7 per cent), respectively.

Table 1. *Errors and complications in relation to the type of surgery*

	I Patients (n)	II Operative procedures (n)	III Entries in complication registry (n)	IV Patients with ≥1 entry in complication registry (n)	V Complication rate (IV / I) (%)	VI Entries registered as error (n)	VII Patients with ≥1 error registered (n)	VIII Error incidence (VII / I) (%)
Vascular Surgery	989	2188	515	280	28,3	108	91	9,2
Gastro-intestinal Surgery	2212	4439	1252	630	28,5	192	158	7,1
Trauma Surgery	1093	2101	347	231	21,1	108	95	8,7
Breast Surgery	541	1126	151	122	22,6	35	32	5,9
Thoracic Surgery	101	330	93	50	49,5	13	10	9,9
General Surgery	3294	4674	481	306	9,3	156	129	3,9
Head and Neck Surgery	154	200	27	20	13,0	7	7	4,5
Nonoperative treatment	3737	N/A	552	394	10,5	254	213	5,7
Total	**12121**	**15058**	**3418**	**2033**	**16,8**	**873**	**735**	**6,1**

Severity grade

Table 2 shows the errors and the Clavien severity grades. Further, the three most frequent types of errors for each of the five TRACS codes with the highest incidence are presented. Of all errors, 827 (94.7 per cent) had no lasting effects for the patient (grade I, IIa and IIb), although almost a quarter of the errors required major additional interventions to counteract the effect of the error (grade IIb).

Type of errors

Besides the errors presented in table 2, drug errors (TRACS 8502) included errors in prescription (n=23) and in administering the drugs (n=24). Anesthetic complications (TRACS 8501) included six cases of iatrogenic injuries, for instance damaged teeth and five cases of unintended extubations. Errors in technique were the most frequent, 188 (21.5 per cent). Errors that contributed to death were error in diagnosis, delay in diagnosis, error in judgement, error in technique and delay to operating room for surgery. Errors in technique were the most frequent to cause permanent injury (grade III) in 28 cases (14.9 per cent), many of which were iatrogenic nerve injuries. Errors in technique were the most frequent to require the patient to be reoperated (grade IIb) in 114 cases (60.6 per cent). Errors in the hospital record (incomplete hospital record) and delay to operating room were mostly benign, since 87 errors (98.9 per cent) were classified as Clavien grade I.

Table 2. *Error as registered by TRACS codes and severity grade according to Clavien showing the three most common types of errors for the five most prevalent codes*

TRACS code	Description	Grade I		Grade IIa		Grade IIb		Grade III		Grade IV		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
9009	error in technique	44	23,4	**1**	0,5	**114**	60,6	**28**	14,9	**1**	0,5	188	100,0
	insufficient or incomplete or incorrectly performed therapeutic procedure	30	16,0	0	0,0	82	43,6	0	0,0	1	0,5	113	60,1
	iatrogenic injury	5	2,7	0	0,0	25	13,3	28	14,9	0	0,0	58	30,9
	insufficient or incomplete nursing procedure	4	2,1	1	0,5	3	1,6	0	0,0	0	0,0	8	4,3
8599	**other miscellaneous**	**115**	77,2	**1**	0,7	**33**	22,1	**0**	0,0	**0**	0,0	149	100,0
	accidental dislocation of drains/ nasogastric tubes/iv lines	37	24,8	0	0,0	28	18,8	0	0,0	0	0,0	65	43,6
	miscommunication between patient and hospital staff/among hospital staff	32	21,5	0	0,0	2	1,3	0	0,0	0	0,0	34	22,8
	retained drains, gauzes or stitches in wound	11	7,4	0	0,0	1	0,7	0	0,0	0	0,0	12	8,1
9008	**error in judgement**	**98**	68,5	**9**	6,3	**32**	22,4	**3**	2,1	**1**	0,7	143	100,0
	error in pre- or nonoperative treatment plan	24	16,8	3	2,1	6	4,2	0	0,0	0	0,0	33	23,1
	error in choice of (part of the) operative procedure	12	8,4	0	0,0	16	11,2	1	0,7	0	0,0	29	20,3
	error in choices in preoperative preparation	22	15,4	0	0,0	0	0,0	0	0,0	1	0,7	23	16,1
9003	**delay to operating room**	**112**	96,6	**1**	0,9	**1**	0,9	**1**	0,9	**1**	0,9	116	100,0
	due to inadequate preoperative evaluation/preparation	33	28,4	1	0,9	0	0,0	0	0,0	1	0,9	35	30,2
	due to lack of operating room capacity	35	30,2	0	0,0	0	0,0	0	0,0	0	0,0	35	30,2
	due to lack of MCU or ICU capacity	31	26,7	0	0,0	0	0,0	0	0,0	0	0,0	31	26,7
9010	**incomplete hospital record**	**87**	98,9	**1**	1,1	**0**	0,0	**0**	0,0	**0**	0,0	88	100,0
	wrong side or wrong body-part described	47	53,4	0	0,0	0	0,0	0	0,0	0	0,0	47	53,4
	other essential information not recorded,	19	21,6	1	1,1	0	0,0	0	0,0	0	0,0	20	22,7
	incomplete or erroneous no documentation of operative procedure	11	12,5	0	0,0	0	0,0	0	0,0	0	0,0	11	12,5
9006	**delay in diagnosis**	40	78,4	**1**	2,0	**5**	9,8	**4**	7,8	**1**	2,0	51	100,0
8502	**drug**	**42**	89,4	**1**	2,1	**2**	4,3	**2**	4,3	**0**	0,0	47	100,0
9004	**delay in md response**	**35**	83,3	**2**	4,8	**3**	7,1	**2**	4,8	**0**	0,0	42	100,0
9007	**error in diagnosis**	**20**	74,1	**0**	0,0	**5**	18,5	**1**	3,7	**1**	3,7	27	100,0
8501	**anaesthetic complication**	**8**	50,0	**1**	6,3	**7**	43,8	**0**	0,0	**0**	0,0	16	100,0
9005	**delay in obtaining consultation**	**6**	100,0	**0**	0,0	**0**	0,0	**0**	0,0	**0**	0,0	6	100,0
	Total	**607**	69,5	**18**	2,1	**202**	23,1	**41**	4,7	**5**	0,6	873	100,0

Discussion

This study shows that error is a common problem in surgery, occurring in up to six per cent of all admissions. In this study up to 70 per cent of errors were grade I events, with little or no consequences for the patient. Some errors however, had significant consequences, either resulting in death or permanent damage to the patient, in this study in one out of every 20 patients. This study further shows there are many near misses without consequences that can be recorded prospectively and analyzed in error prevention programs.

In a systematic review, it was found that the median incidence of adverse events was 9.2 per cent and of these almost half of these events were preventable[9]. Since these studies used retrospective chart review methods to identify adverse events, near misses will be less frequently identified. In agreement, a study comparing different methods of identifying adverse events found that prospective methods were better at identifying preventable adverse events[22]. Thus, the study found an incidence of 3.5-6.4 per cent for preventable adverse events in patients admitted to medical, surgical and obstetric wards, depending on the methods used[22]. The results from the present investigation show a similar incidence of error ranging from 3.9 to 9.9 per cent depending on the surgical subspecialty under investigation. Studies addressing the incidence of errors in surgical patients report an incidence of error of 10.5 per cent and 6.9 per cent respectively[6,23]. These figures are quite similar to the results in the present study.

The finding in the present study that up to 70 per cent of errors are grade I events, suggests that a large proportion of events are near misses, although by definition[18] not all grade I errors are near misses. The common cause hypothesis supports the use of near misses for injury prevention programs[10,11]. Thus, for many error types, the incidence of near misses by far outnumbers the incidence of errors that do have consequences. Hence, if the common cause hypothesis applies to the surgical field, which is likely, the registration and analysis of near misses may signal flaws in provided healthcare well before serious injury occurs. Further, the nature of errors in the present study, suggests that many of these are preventable. Prospective registration of medical errors and near misses might be of great value in quality improvement programs[12] but is, unlike registration of complications, rarely performed. Prospective registration of errors may improve quality of care when the database is regularly evaluated for patterns of errors to identify latent conditions[24] and to identify processes that may have contributed to errors. Besides this, registration of errors might contribute to a surgical Hawthorne effect: outcomes tend to improve when surgeons know they are being evaluated[25]. Even with an accurate error registry however, the most difficult step to improve quality of care is to bring about change in surgical practice[26]. Therefore, when introducing registry systems to identify preventable errors, care must be taken not only to identify conditions that may lead to error, but also to set up systems to bring about change in practice.

Errors may have significant consequences, in the present study in up to 30 per cent of events. Although the differences between the types of errors are probably too small to draw any firm conclusions, in the present investigation errors in technique were

the most frequent errors, accounting for 21.5 per cent of all errors. This finding is in accordance with a previous study on complications and error in surgical patients[27]. In another study on medical errors, technical failure was also one of the most frequent errors encountered[23]. In contrast, nurses are more likely to register medication errors, which is illustrated by the findings of a study on adverse events, with more than 90 per cent of events recorded by nurses[28]. The most common events (33 per cent) were medication related, and surgical technical errors were hardly recorded. Thus, involving both nurses and doctors in adverse events registries may increase the accuracy of these systems.

The present study has some limitations. As compared to retrospective studies addressing the incidence of adverse events, the study sample is rather small. Further, since the medical records were not screened for missed errors, the true incidence of error may be higher than the incidence found in the present investigation. Especially near misses and errors that had no significant consequences may be susceptible to underreporting. A major part of the registration of complications was done by residents, and in other centers it has been shown that residents do not register complications correctly[29]. Previous studies by the authors' group have shown, however, that the proportion of complications that is captured by the registry used in the present study is fairly high. The proportion of complications adequately detected by the registry was 73 per cent and 90 per cent respectively[20,30], suggesting that the registry system used is highly accurate in recording complications. Ideally, there should be a standard to which the error in the registry could be compared including the proportion of errors that the system captures. It has therefore been suggested to conduct a study where trained expert observers are present during the operation and their findings are compared to the self-reported errors in the registry[31]. The problem of underreporting of errors does in some ways limit the conclusions that can be drawn from the study. The true incidence of error in surgery in general and the relative incidence of specific error types cannot be known, since some types of error may be more susceptible to underreporting than other types of errors. However, a major strength of the present study is the completeness and reliability of all recorded data due to a prospective recording in a structured electronic medical record system.

Conclusion

Errors are a common in surgery and have serious consequences in up to 30 per cent of the cases. Prospective registration of medical errors, and near misses, may provide excellent opportunities for prevention and may improve quality of care by reducing the incidence of errors with major consequences.

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Chapter 4

The impact of complications on Quality of Life following colorectal surgery: A prospective cohort study to evaluate the Clavien-Dindo classification system

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Submitted

Abstract

Introduction

This prospective cohort study was performed to evaluate the impact of complications on Quality of Life (QoL) in colorectal surgery and assess the relationship between Clavien-Dindo grade of complications and QoL. Registering complications is important, since complications are used as outcome measures. The Clavien-Dindo complication classification (CDCC) is often reported. The system is promising, but has not been evaluated by relating the classification's severity grades to patient reported outcome measures.

Methods

Patients undergoing colorectal surgery were evaluated prospectively over one year using the abbreviated World Health Organization Quality of Life (WHOQOL-Bref) questionnaire. Patient data were prospectively recorded and complications were classified using the CDCC. Postoperative QoL in patients with minor and severe complications was compared to QoL in patients without complications using a general linear model. The relationships between CDCC and QoL were examined using correlations and multivariate regression.

Results

Of 218 patients, 130 (59.6%) had complications. In patients with severe complications there was a greater decrease in overall QoL (p=0.043), QoL-physical (p<0.001) and QoL-psychological domain (p=0.013) in the first six postoperative weeks, whereas patients with minor complications had QoL scores comparable to patients without complications. Change in QoL at six weeks significantly correlated with CDCC grade, especially in the physical domain (spearman's rho -0.287, p<0.001). Presence of severe complications was an independent predictor of Overall QoL, QoL-physical domain and QoL-psychological domain at six weeks.

Conclusion:

Severe complications are associated with reduced postoperative QoL. CDCC grade negatively correlates with change in QoL in the early postoperative period. These findings support the theoretical framework of the CDCC.

Introduction

Complications in surgery are an important cause of morbidity and mortality. They may result in increased length of hospital stay, repeated surgery, additional medical treatment, legal issues and increased costs[1-5]. Since complications are among the most frequently reported endpoints to evaluate surgical treatment[6], it is very important that a standardized severity grading system for complications is used throughout the literature. Over the years, the Clavien-Dindo system[7] for classifying complications has been reported with increasing frequency in surgical literature[8]. It has been used in liver surgery, pancreatic surgery, and urologic procedures[9-12]. Efforts have been made to validate the system using both input from caregivers as well as patients[13]. However, the system has not been validated by relating the classification's severity grades to well accepted patient reported outcome measures, such as Quality of Life (QoL). In fact, the impact of complications has hardly been examined from the patients' perspective. Although it seems intuitive that complications adversely affect QoL, the degree to which QoL is affected is unknown. It is therefore also unclear, whether complications that are considered more severe in the CDCC (i.e. those with a higher severity grade) are related to reduced QoL scores. Cross-sectional studies evaluating QoL in patients that had undergone colorectal surgery found an association between postoperative complications and decreased long-term QoL[14,15,16]. Considering the design of these studies, the validity of the results is questionnable[17]. QoL-scores between groups cannot be compared, whereas comparing change in QoL over time is valid. QoL scores following an intervention or event of individual patients should therefore be compared to QoL scores prior to the event[17].

This prospective cohort was designed to evaluate the impact of complications on QoL in colorectal surgery. An additional purpose was to assess whether the severity of complications, assessed by the Clavien-Dindo system, was associated with postoperative changes in QoL.

Methods

Patients

The study was conducted in a secondary referral hospital which also serves as a level 1 trauma center, with a capacity of 673 beds. The surgical department consists of 12 surgical residents and 12 consultant surgeons. All patients referred to the surgical department of our hospital for elective colorectal surgery from May 2007 until September 2010 were asked to participate in this prospective cohort study. Exclusion criteria were insufficient knowledge of the Dutch language to complete the questionnaires, psychiatric or neurologic illnesses that preclude adequate assessment by questionnaires and incurable malignancies at primary presentation or diagnosed during the primary operation. All patients provided written informed consent. The study was approved by the local medical ethics committee.

Complications

In accordance with the definition of a complication by the Association of Surgeons of the Netherlands (ASN), we defined a complication as "a condition or an event, unfavorable to the patient's health, causing irreversible damage or requiring a change in therapeutic policy"[18]. The methods for registration and classification have been described in detail elsewhere[19]. The severity of the complication was graded using the Clavien-Dindo system[7]. In this system the severity of the complication is defined by its consequences. Complications that are deviations from the normal postoperative course and need no, or only minor treatment are classified as grade I. Grade II complication require pharmacological treatment. When additional diagnostic or therapeutic procedures are necessary, complications are grade IIIa when performed under local anesthesia, and grade IIIb when under general anesthesia. Grade IV complications are life-threatening complications that require intensive care unit (ICU) management and grade V complications are those that result in death of the patient. The classification system has gained in popularity after its introduction in 2004 and is currently used throughout the world[8]. For the analysis investigating the relation between complications and QoL in patients with more than one complication, the complication with the highest Clavien-Dindo grade in the first year was used in the analysis. Patients with complications were stratified into two groups: grade I and II complications were grouped as minor complications (MC) and grade III, grade IV and grade V complications were grouped as severe complications (SC) as was described previously[14]. These two groups were compared with patients without complications (NC).

Since the registration and coding of complications is known to be sometimes incomplete and inconsistent[20], all patient's files were reviewed for non-recorded complications up to one year postoperatively.

Questionnaires

To evaluate Quality of life, the World Health Organization Quality of Life assessment instrument (short version, WHOQOL-Bref)[21] was used. The Dutch version has been validated in the general population[22]. The WHOQOL-Bref is the short version of the

WHOQOL-100 and has 24 questions belonging to four domains (Physical health, Psychological health, Social relationships, Environment) and two questions belonging to the general evaluative facet called 'Overall QOL and general health'. The WHOQOL-BREF has a 5-point Likert response scale. Higher scores indicate a better quality of life. The WHOQOL-Bref has a good reliability and validity[21] as well as a good sensitivity to change[23].

All patients were asked to complete the WHOQOL-Bref questionnaire at four different moments; prior to surgery (Time0), 3 days after surgery, or as soon as possible if the patients' condition would not allow filling out the questionnaire at the third postoperative day (Time1) and 6 weeks post-operatively or, if still hospitalized at 6 weeks after the primary operation, 6 weeks after discharge (Time2), and 1 year post-operatively (Time3). These moments were chosen for the following reasons. Time0 obviously serves as the baseline measurement, prior to surgery. Time1 was chosen at 3 days postoperatively to evaluate the effect of the operative procedure, since most complications by then have not developed. Time2 was chosen to get information on the short term effect of complications, whilst minimizing patient discomfort, since most minor complications will have resolved by then. Time3 was chosen at one year, to evaluate the long term effects of complications. Change in QoL over time for each individual patient at TimeX was calculated by subtracting the value of TimeX from the value Time0, thus representing the change in QoL from Time0 to TimeX.

Missing data

Single missing questions were manually imputated, using responses to similar items of other questionnaires used in this study for other purposes (Center for Epidemiological Studies-Depression Scale (CES-D), State Trait Anxiety Inventory (STAI) and the Medical Outcome Study-Short Form-36 (SF-36)). When questionnaires were completely missing these were excluded from the analysis. The proportion of missing data was analyzed and is presented in the results section.

Statistical analysis

Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS) version 18.0.

Patients without complications were compared to patients with minor and patients with severe complications. Differences between groups were evaluated using the chi-square test. Differences between the three groups were evaluated using one-way ANOVA with Bonferroni correction for multiple comparisons, or the Kruskall-Wallis test in case of nonparametric data. Consequences of complications in terms of QoL were examined using a general linear model for repeated measurements, comparing patients without complications to patients with minor and severe complications. The effect of time on QoL, the difference in changes in QoL over time between the groups and the absolute difference in QoL were thus evaluated. A value of Eta^2 of 0.01 was considered a small effect, 0.06 moderate and 0.14 was considered a large effect[24]. To evaluate the relation between Clavien-Dindo grade and change in QoL, Spearman's rho was used to determine correlation between these variables. When a significant correlation

was found, standard multivariate linear regression was used (backward method), to determine whether presence of minor and severe complications (as a dummy variable) was an independent predictor of QoL. Other independent variables included in the model were age, sex, type of operation (as a dummy variable), presence of malignancy, presence of comorbidity, and formation of a stoma.
Using G*power (version 3, http://www.gpower.hhu.de)[25], a sample size of 165 patients, of which 42.5% with complications was deemed adequate to achieve a power of 80 percent with an alpha first-level error of 0.05. Since we expected 33% non-responders and dropouts, we aimed for a total inclusion of 250 patients.

Results

During the study period 251 patients consented to participate in the study. Of these patients, 11 withdrew their consent prior to Time0, 8 patients did not return the Time0 questionnaire, and 14 included patients appeared to already have incurable disease at the time of the initial operation. Therefore, data from 218 patients were analyzed.
Baseline patient characteristics are shown in table 1. Patients with complications had more co-morbidity but were otherwise comparable. In table 2, the treatment outcomes are shown. Patients with complications had a longer total hospital stay as well as ICU stay, were more frequently readmitted and re-operated, more frequently admitted to the ICU, and more often had a stoma post-surgery. Postoperative mortality both at six weeks and one year postoperatively was higher in patients with severe complications.

Complications
Of the 218 patients, 130 (59.6%) experienced complications. Seventy-three (33.5%) patients had minor complications, and 57 (26.1%) had severe complications. Patients with SC had a median of 3 (IQR 1-4) complications whereas patients with MC had a median of 1 (IQR 1-1) complications, $p<0.001$. Of all patients with complications, 120 (92.3%) had complications within six weeks of the primary operation or admission. Seventy-one patients (32.6%) underwent one or more reoperations, of which 48 (67.6%) were due to a complication. Of the patients without complications, 1 patient (1.1%) died during the first postoperative year. Of the patients surviving their initial complication, two died within the first postoperative year, 1 patient (1.4%) with MC and 1 patient with SC($p=0.929$). Five patients (3.8%) died as a direct consequence of their complications.
Table 3 shows the complication with the highest Clavien-Dindo grade for each patient. Some complications require explanation. The 4 grade I intra-abdominal abscesses were rectal stump abscesses that were transrectally drained in the ward or outpatient department. The iatrogenic injuries in grade I and II were a nosebleed due to a nasogastric tube that was controlled by tamponade, a minor bladder injury that was directly repaired at the initial procedure, and iatrogenic injury of the spleen that was controlled using a hemostatic agent during the primary operation. The Grade IIIa anastomotic leak occurred following a low anterior resection with protective ileostomy and led to a fistula that was controlled by endosponges and vacuum assisted closure under local anesthesia.

***Table 1**. Baseline patient characteristics*

	Patients without complications		Patients with minor complications		Patients with severe complications		
	n	%	n	%	n	%	*p*
Number of patients (n)	88	100.0	73	100.0	57	100.0	
Age (mean±SD)*	59.9±14.64	-	64.1±12.2	-	63.4±13.2	-	0.113
Male sex (n)	44	50.0	44	60.3	34	59.6	0.344
ASA class (n)							
1	22	25.0	12	16.4	5	8.8	
2	49	55.7	49	67.1	36	63.2	
3	17	19.3	12	16.4	16	28.1	0.080
Any comorbidity (n)	40	45.5	38	52.1	42	73.7	0.003
Cardiac disease	13	14.8	15	20.5	15	26.3	0.228
Hypertension	27	30.7	24	32.9	27	47.4	0.101
Pulmonary disease	9	10.2	10	13.7	15	26.3	0.029
Renal disease	4	4.5	0	0.0	0	0.0	0.049
Diabetes	4	4.5	10	13.7	7	12.3	0.107
Neurologic disease	3	3.4	10	13.7	5	8.8	0.061
Psychiatric disease	4	4.5	2	2.7	1	1.8	0.623
Diagnosis (ICD-10)							
C18 - Malignant neoplasm of colon	32	36.4	24	32.9	17	29.8	
C19 - Malignant neoplasm of rectosigmoid junction	9	10.2	12	16.4	13	22.8	
C20 - Malignant neoplasm of rectum	14	15.9	17	23.3	11	19.3	
D12 - Benign neoplasm of colon. rectum. anus and anal canal	13	14.8	6	8.2	9	15.8	
K50.9 - Crohn's disease. unspecified	4	4.5	3	4.1	2	3.5	
k51 - Ulcerative colitis	3	3.4	0	0.0	2	3.5	
K57 - Diverticular disease of intestine	9	10.2	5	6.8	2	3.5	
Other	4	4.5	6	8.2	1	1.8	0.414
Tumour stage (n)							
Carcinoma in situ	3	3.4	2	2.7	1	1.8	
I	12	13.6	13	17.8	9	15.8	
II	24	27.3	16	21.9	20	35.1	
III	17	19.3	23	31.5	11	19.3	
IV	0	0.0	0	0.0	1	1.8	0.470
Preoperative stoma (n)	10	11.4	9	12.3	5	8.8	0.806

SD= Standard deviation, ICD= International Classification of Disease, ASA= American Society of Anesthesiologists; All p-values are calculated using Chi^2 test, unless stated otherwise; *one-way ANOVA

Table 2. *Treatment outcome*

	Patients without complications		**Patients with minor complications**		**Patients with severe complications**		
	n	%	n	%	n	%	*p*
Number of patients	88	100.0	73	100.0	57	100.0	
Primary procedure							
Ileocecal resection	4	4.5	3	4.1	3	5.3	
Right hemicolectomy	25	28.4	18	24.7	12	21.1	
Transverse colon and left hemicolectomy	3	3.4	2	2.7	3	5.3	
Sigmoidectomy	21	23.9	18	24.7	11	19.3	
Subtotal colectomy	6	6.8	3	4.1	5	8.8	
Rectal resection	13	14.8	17	23.3	16	28.1	
Proctocolectomy	1	1.1	0	0.0	2	3.5	
Rectopexia	2	2.3	2	2.7	0	0.0	
Loop ileostomy reversal	2	2.3	2	2.7	0	0.0	
Colostomy reversal	5	5.7	2	2.7	4	7.0	
Loop colostomy formation	2	2.3	2	2.7	0	0.0	
Other	4	4.5	4	5.5	1	1.8	0.821
Wound classification							
Clean	2	2.3	2	2.7	0	0.0	
Clean-contaminated	78	88.6	61	83.6	52	91.2	
Contaminated	8	9.1	10	13.7	5	8.8	0.604
Postoperative chemotherapy	12	13.6	15	20.5	4	7.0	0.089
Cancer progression or recurrence	2	2.3	4	5.5	1	1.8	0.397
Postoperative -ostomy	22	25.0	29	39.7	37	64.9	<0.001
Total hospital stay (days; median. IQR)*	7 (6-9)		12(8-16)		29(15.5-55)		<0.001
Patients readmitted	8	9.1	23	31.5	36	63.2	<0.001
Patients reoperated <6 weeks	2	2.3	8	11.0	40	70.2	<0.001
Patients reoperated <1 year	9	10.2	12	16.4	48	84.2	<0.001
Patients admitted to ICU	5	5.7	11	15.1	36	63.2	<0.001
Total ICU stay (days; median. IQR)*	0 (0-0)		0(0-0)		1(1-7)		<0.001
Died <6 weeks or during admission	0	0.0	0	0.0	3	5.3	0.014
Died < 1 year	1	1.1	1	1.4	5	8.8	0.021

IQR = Inter Quartile Range, ICU=Intensive Care Unit; All p-values calculated using Chi2 test, unless stated otherwise;
* Kruskal-Wallis

Table 3. *Complications with the highest Clavien-Dindo Grade for all 130 patients with complications*

Grade I (n=40)	n	%	**Grade IIIb (n=32)**	n	%
Wound infection	20	15.4	Intra-abdominal abscess	8	6.2
Postoperative ileus or Gastroparesis	4	3.1	Bowel evisceration	6	4.6
Intra-abdominal abscess	4	3.1	Anastomotic Leak	4	3.1
Incisional hernia	2	1.5	Wound infection	4	3.1
Bladder retention	3	2.3	Incisional hernia	3	2.3
Peroperative iatrogenic injury	2	1.5	Necrotising intestine	2	1.5
Phlebitis peripheral vein	2	1.5	Peroperative iatrogenic injury	2	1.5
Electrolyte disturbance	1	0.8	Postoperative ileus or gastroparesis	1	0.8
Phimosis	1	0.8	Sepsis	1	0.8
Readmission	1	0.8	Pleural empyema	1	0.8
Grade II (n=33)	n	%	**Grade IVa (n=1)**	n	%
Urinary tract infection	13	10.0	Peroperative iatrogenic injury	1	0.8
Pneumonia	8	6.2			
Congestive heart failure	2	1.5	**Grade IVb (n=11)**	n	%
Gastroenteritis	2	1.5	Anastomotic Leak	8	6.2
Myocardial infarction	1	0.8	Intra-abdominal abscess	1	0.8
Cardiac arrhythmia	1	0.8	Respiratory failure	1	0.8
Peroperative iatrogenic injury	1	0.8	Necrotising intestine	1	0.8
Allergic reaction to medication	1	0.8	**Grade V (n=5)**	n	%
Wound infection	1	0.8	Anastomotic Leak	3	2.3
Pulmonary embolus	1	0.8	Gastrointestinal hemorrhage	1	0.8
Delirium	1	0.8	Sepsis	1	0.8
Bacteriaemia	1	0.8			
Grade IIIa (n=8)	n	%			
Postoperative ileus or Gastroparesis	4	3.1			
Anastomotic Leak	1	0.8			
Gastrointestinal hemorrhage	1	0.8			
Cardiac arrhythmia	1	0.8			
Acute cholecystitis	1	0.8			

There were no differences in distribution of types of operation among the three study groups (p=0.86).

Quality of life

There was some data missing in the QoL questionnaires. For Time0 0.9% of single missing answers were imputated as described in the methods section, for Time1, Time2 and Time3 these were 0.8%, 0.8% and 0.5% respectively. The number of completely missing questionnaires were 2.6% for Time0, 14.5% for Time1, 11.0% for Time2 and 16.6% for Time3.

Figure 1A to 1C show patients' scores on Overall QoL, QoL–physical domain and QoL-psychological domain across time, respectively, for the three patient groups. No differences were observed for QoL-social domain and QoL-environmental domain.

For Overall QoL, a significant difference existed for change in QoL at Time2 for NC versus SC (0.19±1.60 versus -0,55±1,83; p=0.043) and MC versus SC (0.29±1.52 versus -0.55±1.83; p=0.022) , but not NC versus MC (0.19±1.60 versus 0.29±1.52; p=1.00). No significant differences existed in change in Overall QoL for Time1 and Time3.

With regard to change in QoL-physical domain a significant difference existed at Time2 between NC and SC (0.11±3.12 versus -2.00±2.81; p<0.001) but not between NC and MC(0.11±3.12 versus -1.00±2.68; p=0.074) and MC and SC (-1.00±2.68 versus -2.00±2.81; p=0.225). No significant differences were observed in change in

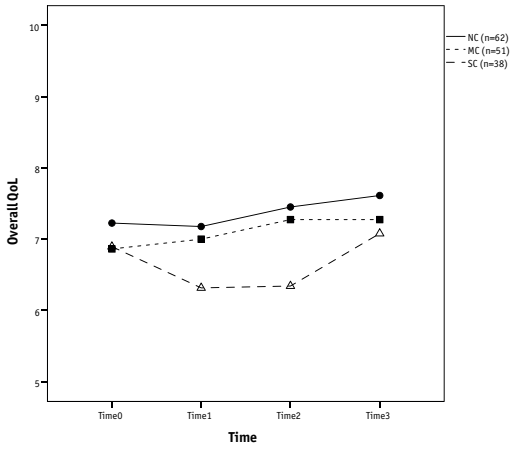

Figure 1A *Overall QoL. A difference in QoL between the groups (p=0.049, Eta2=0.04) as well as an effect of time (Eta2=0.029, p=0.006) is observed. There was no significant difference between the groups with respect to change in QoL over time (p=0.134). NC=patients without complications, MC= patients with minor complications, SC= patients with severe complications.*

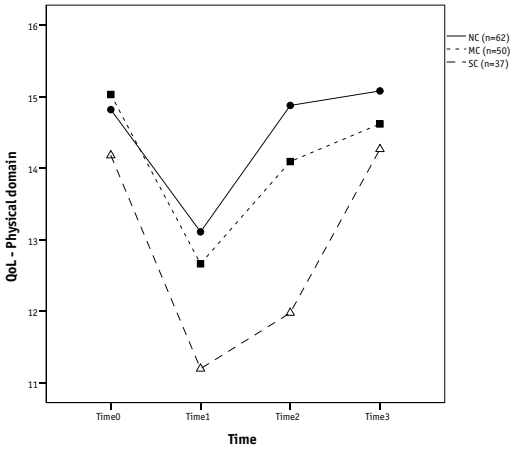

Figure 1B *QoL – Physical domain shows a significant difference between the groups with respect to changes in QoL over time (p=0.002, eta2=0.070). Compared to the NC group and MC group, the SC group experienced less improvement in QoL between Time1 and Time2. A difference in QoL between the groups was found (p=0.010, Eta2=0.061) as well as an effect of time (Eta2=0.39, p<0.001). NC=patients without complications, MC= patients with minor complications, SC= patients with severe complications.*

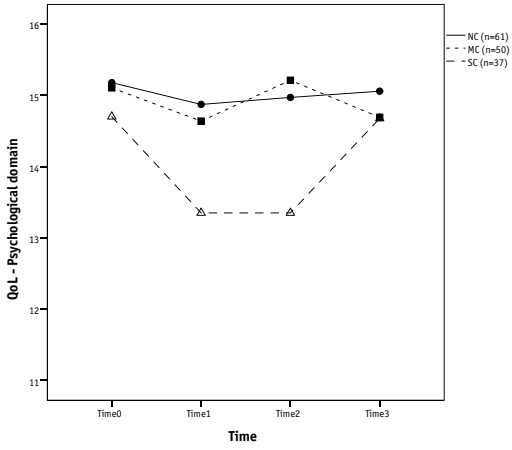

Figure 1C QoL – *Psychological domain shows a difference between the groups with respect to changes in QoL over time (p=0.001, eta2=0.114). Compared to the NC and MC groups, the SC group experienced a worse Psychological QoL score at Time1 and Time2. At Time3, the scores of the SC group increased to a level comparable to the other groups. There was an effect of time (Eta2=0.04, p=0.010). but no significant difference in QoL between the groups was found (p=0.104, Eta2=0.031). NC=patients without complications, MC= patients with minor complications, SC= patients with severe complications.*

QoL-physical domain for Time1 and Time3. Change in QoL-psychological domain was significantly different at Time2 for both NC versus SC (-0.17±2.19 versus -1.28±2.36; p=0.013) and MC versus SC (0.03±1.67 versus -1.28±2.36; p=0.004), but not NC versus MC (-0.17±2.19 versus 0.03±1.67; p=1.00). No significant differences existed in change in QoL-psychological domain for Time1 and Time3. No differences were observed in change in QoL for Time1, Time2 and Time3 in both the social and environmental domains (data not shown).

Change in overall quality of life at Time2 significantly correlated to Clavien-Dindo grade (spearman's rho -0.154, p=0.034). Furthermore, change in QoL-physical domain at Time2 (spearman's rho -0.287, p<0.001) and change in QoL- psychological domain at Time2 (spearman's rho -0.190, p=0.009) both significantly correlated to Clavien-Dindo grade as well. No significant correlations were found between Clavien Dindo grade and the social and environmental domains at Time2. With regard to Time1 and Time3 significant correlations were found neither for Overall Qol, nor for any of the four domains.

Table 4 shows the unique predictors for change in Overall Quality of life, change in QoL-physical domain and change in QoL-psychological domain at Time2 as identified by backward linear regression.

Table 4. *Unique predictors for change in Overall Quality of life, change in QoL-physical domain and change in QoL-psychological domain at Time2 as identified by backward linear regression*

Dependent variable	F	p-value	Adjusted R2	Predictor Variable	standardised b	p-value
Change in Overall QoL	5.976	0.001	0.073			
				Presence of severe complications	-0.173	0.016
				Left-sided colonic surgery	-0.17	0.030
				Low rectal surgery	-0.225	0.005
Change in QoL-physical domain	7.001	<0.001	0.138			
				Presence of severe complications	-0.23	0.004
				Presence of minor complications	-0.164	0.030
				Left-sided colonic surgery	-0.217	0.005
				Low rectal surgery	-0.279	<0.001
				Presence of comorbidity	-0.132	0.061
Change in QoL-psychological domain	10.169	<0.001	0.089			
				Presence of severe Complications	-0.182	0.013
				Presence of a stoma	-0.207	0.005

Discussion

This study shows that both colorectal surgery with and without complications have an impact on QoL, most notably in the physical and psychological domains. It also shows that patients with severe complications have a more profound decrease in
Overall QoL, QoL-physical domain and QoL-psychological domain in the first 6 postoperative weeks than patients without complications. Quality of life in patients with minor complications is comparable to that of patients without complications. Interestingly, it also showed that QoL is restored to preoperative levels at one year postoperatively in allpatients, regardless of complications. Finally, we showed that the Clavien-Dindo grade was significantly correlated to change in QoL in the first 6 weeks and that the presence of severe complications was an independent predictor of decreased Overall QoL, QoL-physical domain, and QoL - psychological domain at six weeks. The finding that abdominal surgery has a measurable impact on quality of life is in accordance with prior studies[26,27]. These studies however, did not investigate the impact of complications on the postoperative QoL. Studies that did find an association between complications and QoL are the previously mentioned cross-sectional studies[14,15] as well as a prospective study evaluating the predictors of early postoperative QoL after colorectal surgery, which found an association between postoperative complications and anxiety and depression, and also QoL[28]. The finding in our present study that severe complications influence QoL has not been shown before and may in the future have implications for clinical practice. The results of our study may be used to more thoroughly inform patients about the possible impact of complications. Furthermore, Patients with severe complications may benefit from routine psychological counselling, to improve their psychological well-being. A prospective randomised study might be performed to evaluate the effect of psychological interventions on postoperative QoL in patients with severe complications.
The present study prospectively assessed the correlation between Clavien-Dindo grade and change in QoL in the early postoperative period. The finding that the Clavien-Dindo grade significantly correlated to change in QoL in the first 6 weeks supports the theoretical basis of the Clavien-Dindo classification. The Clavien-Dindo classification has a good theoretical basis and is highly intuitive. A main disadvantage however, is that it defines the severity of complications solely from the doctors' point of view. Recently, efforts were made to relate the Clavien-Dindo classification to the perception of the severity of the complication of patients[8,13] by using written clinical scenarios that were evaluated by patients on a 0-100 scale. It was shown that the Clavien-Dindo system correlated with the perceived severity of complications by patients. Until the present study, this was the only evidence available relating the severity of complications and our patients' perception. The present study relates the severity of complications to the validated psychological construct of quality of life, and its findings support the results of the prior studies by Clavien's group that the conceptual framework of the Clavien-Dindo classification is valid.
Quality of life is reduced during the early postoperative period following colorectal surgery, but it is restored to preoperative levels one year after surgery. The finding that

QoL is restored to preoperative levels has also been shown by another study[27]. The finding in the present study that this is the case for both patients with complications and patients without complication has not been shown before. There may be several explanations for this phenomenon. The effects of even severe complications may not last longer than weeks to months, and the detrimental effect on QoL has faded at one year after the operation. For some complications, such as anastomotic leak resulting in a permanent stoma, the effects will last. Therefore other mechanism must play a role in restoring QoL. Patients may (either consciously or unconsciously) employ strategies to cope with the effects of complications and adapt to their new situation. Through coping they will find a new equilibrium, and QoL is restored. These coping mechanisms may explain the lack of association between QoL and the Clavien-Dindo classification at one year. QoL of life at three days postoperatively was not significantly correlated to the presence of complications or Clavien-Dindo classification. The most likely explanation for this may be that most complications have not yet revealed themselves at three days postoperatively, and the effects of complications at this stage therefore are not yet measurable.

Although the results of the study are both valid and unique, the present study also has some drawbacks. As in any questionnaire study, we had a certain amount of missing data. Sometimes patients forgot to or refused to fill out specific items in the questionnaire, or they refused to fill out the complete questionnaire. In the results section, however we reported the amount of missing data, which is fairly acceptable for a questionnaire study. Another potential drawback is the mixture of different diseases and different surgical procedures, although in the multivariate regression analysis we found that presence of severe complications were predictors of postoperative QoL, independent of type of surgery or presence of malignancy. Remarkably, the incidence of complications was rather high. A possible explanation may be that in this study, surveillance for complications was performed very meticulously, and every event that met the criteria for a complication was recorded. It seems unlikely that this is a source of bias. Another drawback is the problem that many facets in life may influence Quality of life, and not all events in the lives of our patients are known to us nor disclosed by our patients. Unfortunately, it is not known what happened to QoL in the early postoperative period between three days postoperatively and 6 weeks, and from six weeks onwards. It would be very interesting to investigate the dynamics of QoL in the first months in more detail in future studies. Although the study gives insight in the effects of complications and supports the theory of the Clavien-Dindo classification, the clinical relevance of the findings in our study is not immediately clear. We do not know whether the differences in QoL have clinical relevance and we do not know whether interventions (i.e. psychological counselling) may help to improve QoL. An advantage of the study is the prospective recording of the clinical data, complications and the QoL questionnaires in a sufficiently large cohort of patients.

Conclusion

Severe complications are independent predictors of a more profound decrease in QoL scores at 6 weeks postoperatively and Clavien-Dindo score negatively correlates with

change in QoL in the early postoperative period. These findings support the validity of the theoretical framework of the Clavien-Dindo classification. Therefore it is recommended that the Clavien-Dindo classification is used as the world-wide gold standard to report postoperative complications.

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Chapter 5

Health status, anxiety and depressive symptoms following complicated and uncomplicated colorectal surgery

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Submitted

Abstract

Objective

To evaluate the impact of complications following colorectal surgery on anxiety, depressive symptoms, and health status.

Introduction: Previously very few studies examined the psychological impact of complications following colorectal surgery. Also in clinical practice, little attention is paid to the psychological impact of complications.

Methods

Patients undergoing colorectal surgery were evaluated prospectively preoperatively and postoperatively at 3 days, 6 weeks and one year, using the CES-D, STAI and SF-36 questionnaires. Patient data and complications were prospectively recorded. Postoperative CES-D, STAI and SF-36 scores in patients with minor and severe complications were compared to scores of patients without complications using a general linear model.

Results

Of 218 patients, 130 (59.6%) had complications. Colorectal surgery significantly increased depressive symptoms and anxiety levels in the same amount in all patient subgroups. Furthermore, it also lowered all domains of health status in all patient subgroups, but not equally. Patients with a severely complicated postoperative course had a larger postoperative decrease in health status, most notably at six weeks postoperatively with the largest effects in the physical-, mental-, social- and vitality domains compared with the other subgroups.

Conclusion

Colorectal surgery has a profound effect on depressive and anxiety symptoms, as well as nearly all domains of health status. Occurrence of severe complications increases the negative effect of colorectal surgery on most domains of health status but do not specifically increase depressive symptoms or anxiety levels. At 6 weeks these effects are most notable, but at one year they have faded.

Introduction

Complications in surgery are important causes of morbidity and mortality. They may result in prolonged length of hospital stay, repeated surgery, or additional medical treatment as well as increased costs and legal issues[1,2,3,4,5]. Furthermore, complications after colorectal surgery are associated with reduced long term Quality of Life (QoL)[6,7,8]. Other psychological sequalae, such as anxiety and depressive symptoms, have been studied less frequently. A cross-sectional study showed that in a sample of 140 patients one year after colorectal surgery, the prevalence of anxiety was 7.8% and the prevalence of depressive symptoms was 37%[9]. While the literature on the impact of complications on QoL is scarce, there is virtually no literature on the impact of complications on anxiety and depressive symptoms after colorectal surgery. A study evaluating the impact of complications after post-mastectomy reconstruction after breast cancer showed increased depressive and anxiety symptoms in case of complications[10].

Another study among 36 patients undergoing colorectal surgery showed that a high proportion of patients had high levels of anxiety prior to surgery and it was suggested that patients undergoing colorectal surgery should be evaluated and provided intervention for clinically relevant anxiety[11]. In patients who survived at least 5 years after colorectal cancer, there were higher rates of depressive symptoms as compared to the general population, even though QoL was better than the reference population[12]. Literature on the impact of surgical complications on depressive symptoms is completely absent. In clinical practice, little attention is paid to the psychological impact of surgical complications, although it seems intuitive that postoperative complications after colorectal surgery may increase patients' levels of anxiety and depressive symptoms and negatively influence mental health in the postoperative period. Since these patients may benefit from psychological counseling, it may be important to assess whether anxiety levels and depressive symptoms are increased in patients experiencing complications after colorectal surgery.

The purpose of this prospective cohort study was to evaluate the effect of complications on patients' anxiety, depressive symptoms and health status following colorectal surgery. This is the first study to prospectively assess the impact of complications on these patient recorded outcome measures.

Methods

Patients

The hospital where this prospective cohort study was conducted is a secondary referral hospital and a level 1 trauma center, with a capacity of 543 beds. The surgical department consists of 12 surgical residents and 12 consultant surgeons. All patients referred to our surgical department for elective colorectal surgery from May 2007 until September 2010 were asked to participate in this prospective cohort study. Exclusion criteria were insufficient knowledge of the Dutch language to complete the questionnaires, psychiatric or neurologic illnesses that preclude adequate assessment by questionnaires, and incurable malignancies at primary presentation or diagnosed during the primary operation. All patients provided written informed consent. The study was approved by the local medical ethics committee.

Complications

In accordance with the definition of a complication by the Association of Surgeons of the Netherlands (ASN), we defined a complication as "a condition or an event, unfavorable to the patient's health, causing irreversible damage or requiring a change in therapeutic policy"[13]. The methods for registration and classification have been described in detail elsewhere[14]. The severity of the complication was graded using the Clavien-Dindo system[15]. In this system the severity of the complication is defined by its consequences. Complications that are deviations from the normal postoperative course and need no or only minor treatment are classified as grade I. A grade II complication requires pharmacological treatment. When additional diagnostic or therapeutic procedures are necessary, they are grade IIIa when performed under local anesthesia or grade IIIb when under general anesthesia. Grade IV complications are life-threatening complications that require ICU management and grade V complications result in death. This classification system is currently used throughout the world[16]. For the analysis investigating the relation between complications and anxiety, depressive symptoms and health status in patients with more than one complication, the complication with the highest Clavien-Dindo grade in the first year was used in the analysis. Patients with complications were stratified into two groups: grade I and II complications were grouped as minor complications (MC) and grade III, grade IV and grade V complications were grouped as severe complications (SC)[6]. These two groups were compared with patients without complications (NC).

Since the registration and coding of complications is known to be sometimes incomplete and inconsistent[17], all patient's files were reviewed for non-recorded complications up to one year postoperatively.

Questionnaires

To assess depressive symptoms the Center for Epidemiological Studies-Depression Scale (CES-D)[18] was used. It is a 20-item scale designed to measure the presence and degree of depressive symptoms. It has a 4-point response scale. For the Dutch population, reliability and criterion validity appear to be good[19]. Shorter versions have

been developed and validated. To minimize the number of items to be answered by the patients, the 16-item CES-D as suggested by Schroevers et al[20] was used. It was found to be a valid assessment of depressive symptoms in both cancer patients and healthy persons. A higher score indicates more depressive symptoms.
To assess anxiety, the State Trait Anxiety Inventory (STAI) was used[21]. The State Trait Anxiety Inventory (STAI) measures both state and trait anxiety. Each version consists of 20 questions with a 4-point response scale. It is a widely used measure with good reliability and validity[22]. In the analysis only state anxiety was used. Higher scores indicate higher anxiety levels.
The Medical Outcome Study-Short Form-36 (SF-36) was used to measure health status. The SF-36 includes one multi-item scale that assesses eight health concepts: 1) limitations in physical activities because of health problems; 2) limitations in social activities because of physical or emotional problems; 3) limitations in usual role activities because of physical health problems; 4) bodily pain; 5) general mental health (psychological distress and well-being); 6) limitations in usual role activities because of emotional problems; 7) vitality (energy and fatigue); and 8) general health perceptions[23]. A high score indicates good health status. The questionnaire has been shown to have good internal consistency and validity[24,25].
All patients were asked to complete the CES-D, STAI and SF-36 questionnaires at four different moments; prior to surgery (Time0), 3 days after surgery, or as soon as possible if the patients' condition would not allow filling out the questionnaire at the third post-operative day (Time1). The third measurement was done 6 weeks post-operatively. If the patient was still hospitalized 6 weeks after the primary operation this questionnaire was filled out 6 weeks after discharge (Time2). The last questionnaire was filled out at 1 year postoperatively (Time3). These moments were chosen for the following reasons. Time0 serves as the baseline measurement, prior to surgery. Time1 was chosen at 3 days postoperatively to evaluate the effect of the operative procedure, since most complications have not yet developed. Time2 was chosen both to minimize patient discomfort, since minor complications will have mostly resolved by then and Time3 was chosen at one year, to evaluate the long term effects of all complications. Since we were only interested in the change of scores over time, we calculated a relative score for anxiety, depressive symptoms and health status, to rule out baseline differences between patient groups. Change in CES-D, STAI and SF-36 scores over time for each individual patient at TX was calculated by subtracting the value of TX from the value T0, thus representing the change in depressive symptoms, anxiety and health status from T0 to TX.

Missing data

Single missing questions were manually imputated, using responses to similar items. When questionnaires were completely missing these were excluded from the analysis. The proportion of missing data was analyzed and is presented in the results section.

Statistical analysis

Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS) version 18.0.

Patients without complications were compared to patients with minor and patients with severe complications. Differences between groups were evaluated using chi-square test. Differences between the three groups were evaluated using one-way ANOVA with Bonferroni correction for multiple comparisons, or the Kruskall-Wallis test in case of nonparametric data. The changes in depressive symptoms, anxiety, and health status were examined using a general linear model for repeated measurements, comparing patients without complications to patients with minor and severe complications. The effect of time on depressive symptoms, anxiety and health status, the difference in changes in depressive symptoms, anxiety and health status over time between the groups and the absolute difference in depressive symptoms, anxiety and health status were thus evaluated. A value of Eta2 of 0.01 was considered a small effect, 0.06 moderate and 0.14 was considered a large effect[26]. Using G*power (version 3, http://www.gpower.hhu.de)[27], a sample size of 165 patients, of which 42.5% with complications was deemed adequate to achieve a power of 80 percent with an alpha first-level error of 0.05. Since we expected 33% non-responders and dropouts, we aimed for a total inclusion of 250 patients.

Results

During the study period 251 patients consented to participate in the study. Of these patients, 11 withdrew their consent prior to Time0, 8 patients did not return the Time0 questionnaire, and 14 included patients appeared to already have incurable disease at the time of the initial operation. Therefore, data from 218 (86.9%) patients were analyzed. Baseline patient characteristics are shown in table 1. Patients with complications were older and had more co-morbidity, especially diabetes and neurologic disease. In table 2, the treatment outcomes are shown. Patients with complications had a longer total hospital stay as well as ICU stay, were more frequently readmitted and re-operated, more frequently admitted to the ICU, and more often had a stoma post-surgery.

Complications

Of the 218 patients, 130 (59.6%) experienced complications in the first year postoperatively. Seventy-three (33.5%) patients had minor, and 57 (26.1%) had severe complications. Patients with severe complications had a median of 3 (IQR 1-4) complications whereas patients with minor complications had a median of 1 (IQR 1-1) complications, $p<0.001$. Of all patients with complications, 120 (92.3%) had these within six weeks of the primary operation or admission. Seventy-one patients (32.6%) underwent one or more reoperations, of which 48 (67.6%) were due to a complication. Of the patients without complications, 1 patient (1.1%) died during the first postoperative year. Of the patients surviving their complication, two died within the first postoperative year, 1 patient (1.4%) with minor complications and 1 patient with severe complications ($p=0.929$). Five patients (3.8%) died as a direct consequence of their complications.

***Table 1**. Baseline patient characteristics*

	Patients without complications		Patients with minor complications		Patients with severe complications		
	n	%	n	%	n	%	p
number of patients (n)	88	100.0	73	100.0	57	100.0	
Age (mean±SD)*	59.9±14.64	-	64.1±12.2	-	63.4±13.2	-	0.113
Male sex (n)	44	50.0	44	60.3	34	59.6	0.344
ASA 1 (n)	22	25.0	12	16.4	5	8.8	
ASA 2 (n)	49	55.7	49	67.1	36	63.2	
ASA 3 (n)	17	19.3	12	16.4	16	28.1	0.080
Any comorbidity (n)	40	45.5	38	52.1	42	73.7	0.003
Cardiac disease	13	14.8	15	20.5	15	26.3	0.228
Hypertension	27	30.7	24	32.9	27	47.4	0.101
Pulmonary disease	9	10.2	10	13.7	15	26.3	0.029
Renal disease	4	4.5	0	0.0	0	0.0	0.049
Diabetes	4	4.5	10	13.7	7	12.3	0.107
Neurologic disease	3	3.4	10	13.7	5	8.8	0.061
Psychiatric disease	4	4.5	2	2.7	1	1.8	0.623
Diagnosis							
C18 - Malignant neoplasm of colon	32	36.4	24	32.9	17	29.8	
C19 - Malignant neoplasm of rectosigmoid junction	9	10.2	12	16.4	13	22.8	
C20 - Malignant neoplasm of rectum	14	15.9	17	23.3	11	19.3	
D12 - Benign neoplasm of colon. rectum. anus and anal canal	13	14.8	6	8.2	9	15.8	
K50.9 - Crohn's disease. unspecified	4	4.5	3	4.1	2	3.5	
k51 - Ulcerative colitis	3	3.4	0	0.0	2	3.5	
K57 - Diverticular disease of intestine	9	10.2	5	6.8	2	3.5	
Other	4	4.5	6	8.2	1	1.8	0.414
Tumour stage (n)							
Carcinoma in situ	3	3.4	2	2.7	1	1.8	
I	12	13.6	13	17.8	9	15.8	
II	24	27.3	16	21.9	20	35.1	
III	17	19.3	23	31.5	11	19.3	
IV	0	0.0	0	0.0	1	1.8	0.470
preoperative stoma (n)	10	11.4	9	12.3	5	8.8	0.806

All p-values calculated using Chi2 test, unless stated otherwise; *one-way ANOVA

Table 2. *Treatment outcome*

	Patients without complications		Patients with minor complications		Patients with severe complications		
	n	**%**	**n**	**%**	**n**	**%**	**p**
Patients (n)	88	100.0	73	100.0	57	100.0	
Procedure							
Ileocecal resection	4	4.5	3	4.1	3	5.3	
Right hemicolectomy	25	28.4	18	24.7	12	21.1	
Transverse colon and left hemicolectomy	3	3.4	2	2.7	3	5.3	
Sigmoidectomy	21	23.9	18	24.7	11	19.3	
Subtotal colectomy	6	6.8	3	4.1	5	8.8	
Rectal resection	13	14.8	17	23.3	16	28.1	
Proctocolectomy	1	1.1	0	0.0	2	3.5	
Rectopexia	2	2.3	2	2.7	0	0.0	
Loop ileostomy reversal	2	2.3	2	2.7	0	0.0	
Colostomy reversal	5	5.7	2	2.7	4	7.0	
Loop colostomy formation	2	2.3	2	2.7	0	0.0	
Other	4	4.5	4	5.5	1	1.8	0.821
Wound classification							
Clean	2	2.3	2	2.7	0	0.0	
Clean-contaminated	78	88.6	61	83.6	52	91.2	
Contaminated	8	9.1	10	13.7	5	8.8	0.604
Postoperative chemotherapy	12	13.6	15	20.5	4	7.0	0.089
Cancer progression or recurrence	2	2.3	4	5.5	1	1.8	0.397
Postoperative -ostomy	22	25.0	29	39.7	37	64.9	<0.001
Total hospital stay (days; median. IQR)*	7 (6-9)		12(8-16)		29(15.5-55)		<0.001
Patients readmitted	8	9.1	23	31.5	36	63.2	<0.001
Patients reoperated <6 weeks	2	2.3	8	11.0	40	70.2	<0.001
Patients reoperated <1 year	9	10.2	12	16.4	48	84.2	<0.001
Patients admitted to ICU	5	5.7	11	15.1	36	63.2	<0.001
Total ICU stay (days; median. IQR)*	0 (0-0)		0(0-0)		1(1-7)		<0.001
Died < 6 weeks or during admission	0	0.0	0	0.0	3	5.3	0.014
Died < 1 year	1	1.1	1	1.4	5	8.8	0.021

*All p-values calculated using Chi2 test, unless stated otherwise; * Kruskal-Wallis*

Table 3. *Complications with the highest Clavien-Dindo Grade for all 130 patients with complications*

Grade I (n=40)	**n**	**%**	**Grade IIIb (n=32)**	**n**	**%**
Wound infection	20	15.4	Intra-abdominal abscess	8	6.2
Postoperative ileus or gastroparesis	4	3.1	Bowel evisceration	6	4.6
Intra-abdominal abscess	4	3.1	Anastomotic Leak	4	3.1
Incisional hernia	2	1.5	Wound infection	4	3.1
Bladder retention	3	2.3	Incisional hernia	3	2.3
Peroperative iatrogenic injury	2	1.5	necrotising intestine	2	1.5
Phlebitis peripheral vein	2	1.5	Peroperative iatrogenic injury	2	1.5
Electrolyte disturbance	1	0.8	Postoperative ileus or gastroparesis	1	0.8
Phimosis	1	0.8	sepsis	1	0.8
Readmission	1	0.8	pleural empyema	1	0.8
Grade II (n=33)			**Grade IVa (n=1)**		
Urinary tract infection	13	10.0	Peroperative iatrogenic injury	1	0.8
Pneumonia	8	6.2			
Congestive heart failure	2	1.5			
Gastroenteritis	2	1.5			
Myocardial infarction	1	0.8	**Grade IVb (n=11)**		
Cardiac arrhythmia	1	0.8	Anastomotic Leak	8	6.2
Peroperative iatrogenic injury	1	0.8	Intra-abdominal abscess	1	0.8
Allergic reaction to medication	1	0.8	respiratory failure	1	0.8
Wound infection	1	0.8	necrotising intestine	1	0.8
Pulmonary embolus	1	0.8			
Delirium	1	0.8			
Bacteriaemia	1	0.8			
Grade IIIa (n=8)			**Grade V (n=5)**		
Postoperative ileus or gastroparesis	4	3.1	Anastomotic Leak	3	2.3
Anastomotic Leak	1	0.8	Gastrointestinal hemorrhage	1	0.8
Gastrointestinal hemorrhage	1	0.8	sepsis	1	0.8
Cardiac arrhythmia	1	0.8			
Acute cholecystitis	1	0.8			

There were no differences in distribution of types of operation between patients without complications, patients with minor complications and patients with severe complications (p=0.86). Table 3 shows the complication with the highest Clavien-Dindo grade for each patient. The 4 grade I intra-abdominal abscesses were rectal stump abscesses that were transrectally drained in the ward or outpatient department. The iatrogenic injuries in grade I and II were a nosebleed due to a nasogastric tube that was controlled by tamponade, a minor bladder injury that was directly repaired at the initial procedure, and iatrogenic injury of the spleen that was controlled using a hemostatic agent during the primary operation. The Grade IIIa anastomotic leak occurred following a low anterior resection with protective ileostomy and led to a fistula that was controlled by endosponges and vacuum assisted closure under local anesthesia.

Depressive symptoms

There was some data missing. For Time0 0.7% of single missing answers were imputated as described in the methods section, for Time1, Time2 and Time3 these percentages were 0.8%, 0.5% and 0.3% respectively. The percentage of completely missing questionnaires was 1.3% for Time0, 15.1% for Time1, 11.4% for Time2 and 17.0% for Time3.

Figure 1 shows patients' relative scores on the CES-D scale for the three patient groups over time. Scores initially increased and later substantially decreased. There were no significant differences between the groups in changes in CESD scores at any moment.

Anxiety

There was missing data. For Time0 0.4% of single missing answers were imputated as described in the methods section. For Time1, Time2 and Time3 these percentages were 0.5%, 0.3% and 0.3% respectively. Questionnaires were completely missing in 0.4% of patients for Time0, 14.7% for Time1, 12.4% for Time2 and 17.4% for Time3. There were no differences in baseline trait anxiety between the groups (NC 36.1±10.82; MC 35.0±10.71; SC 37.8±11.52; p=0.38). Figure 2 shows changes in the state anxiety scores for the three patient groups over time. It shows that in all groups, anxiety significantly reduced over time. The anxiety levels were never significantly different between the groups.

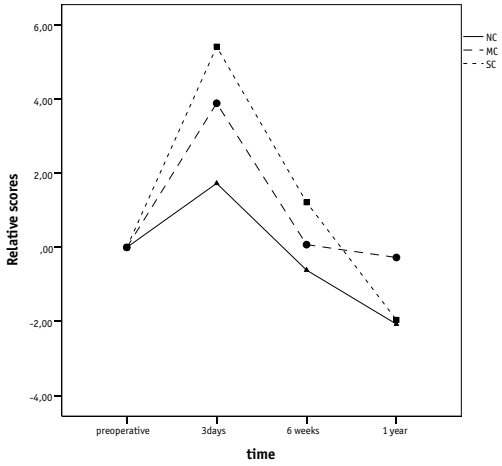

Figure 1. *Depressive symptoms (CES-D). A large effect of time (p<0.001, Eta2=0.249) is observed. There were no differences between the groups (p=0.229) and the pattern of change of CES-D scores over time was not significantly different between the groups (p=0.147). NC=patients without complications, MC= patients with minor complications, SC= patients with severe complications.*

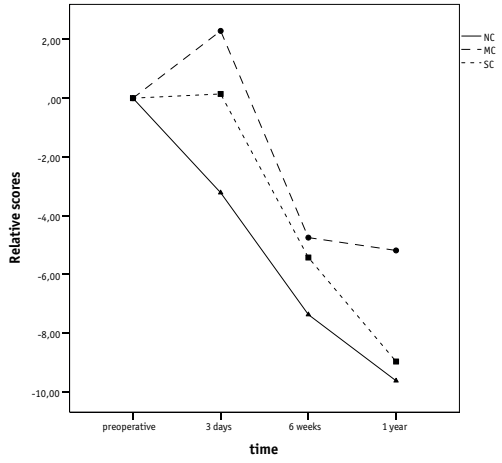

Figure 2*. Anxiety. A large effect of time (p<0.001, Eta2=0.41) is observed. There was no difference in the pattern of change of STAI scores over time (p=0.231) and there was no significant difference between the groups (p=0.070, Eta2=0.038). NC=patients without complications, MC= patients with minor complications, SC= patients with severe complications.*

Health Status

There was slightly more missing data in HS than in the other outcome measures. For Time0 1.0% of single missing answers were imputated as described in the methods section, for Time1, Time2 and Time3 these were 2.0%, 1.0% and 0.6% respectively. The number of completely missing questionnaires were 2.8% for Time0, 14.2% for Time1, 11.5% for Time2 and 17.0% for Time3.

Figure 3A shows the SF-36 domain of limitations in physical activities because of health problems. At 6 weeks (Time2) there was a significant difference between NC and SC (p=0.007) and MC and SC (p=0.018). Figure 3B shows limitations in social activities because of physical or emotional problems. At 3 days (Time1) there was a significant difference between NC and SC (p=0.026) but not MC and SC (p=0.641) whereas at 6 weeks (Time2) there was a significant difference between NC and SC (p<0.001) as well as MC and SC (p=0.001). Figure 3C shows limitations in usual role activities because of physical health problems and figure 3D shows bodily pain. Figure 3E shows general mental health. At 6 weeks (Time2) there was a significant difference between NC and SC (p=0.004) and MC and SC (p=0.024). Figure 3F shows limitations in usual role activities because of emotional problems whereas figure 3G shows vitality (energy and fatigue). There were significant differences in scores at 3 days (Time1) (NC versus SC p=0.047) and 6 weeks (Time2) (NC versus SC p<0.001; NC versus MC p=0.036). Figure 3H shows the domain of general health perceptions. There were only significant differences between the groups at 6 weeks (Time2) (p=0.025 NC vs. SC, p= 0.009 MC vs. SC).

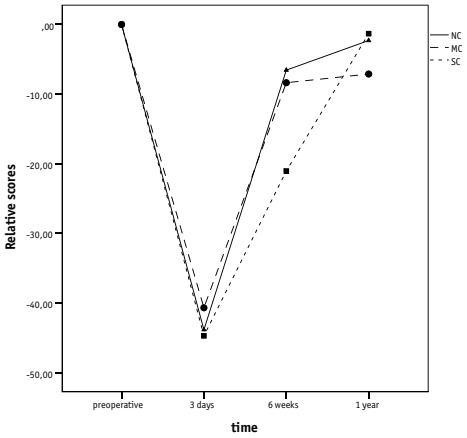

Figure 3A. *limitations in physical activities because of health problems. A large effect of time (p<0.001, Eta²=0.58) is observed. There was a significant difference in the pattern of change of physical functioning over time (p=0.007, Eta2=0.058). But no significant differences between the groups (p=0.513). NC=patients without complications, MC= patients with minor complications, SC= patients with severe complications.*

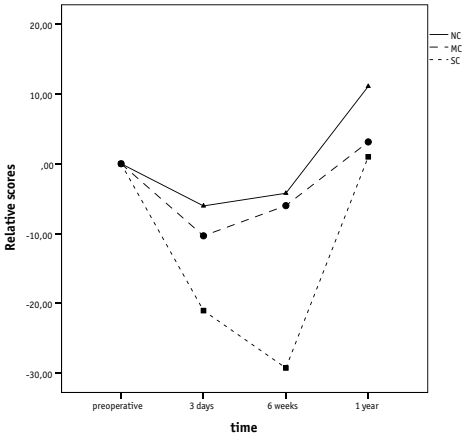

Figure 3B. *limitations in social activities because of physical or emotional problems. A large effect of time (p<0.001, Eta²=0.438) is observed. There was a significant difference in the pattern of change of social functioning over time(p<0.001, Eta2=0.090), as well as a significant difference between the groups (p=0.001, Eta2=0.095). NC=patients without complications, MC= patients with minor complications, SC= patients with severe complications.*

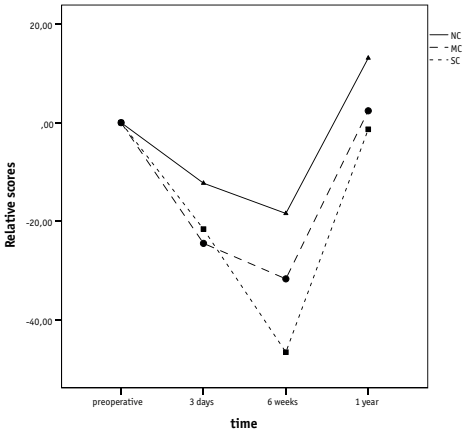

Figure 3C *limitations in usual role activities because of physical health problems. A large effect of time (p<0.001, Eta²=0.481) is observed. There was no significant difference in the pattern of change over time(p=0.102, Eta2=0.036). However, there was a significant difference between the groups (p=0.048, Eta2=0.041). NC=patients without complications, MC= patients with minor complications, SC= patients with severe complications.*

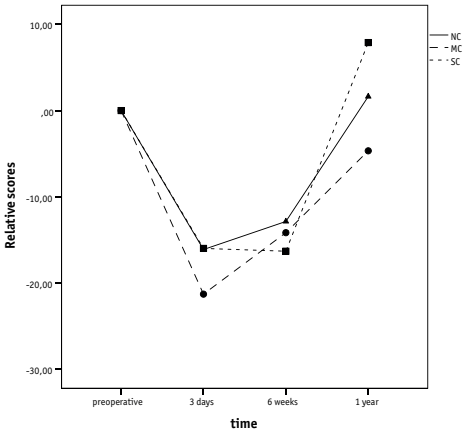

Figure 3D. *Bodily pain. A large effect of time (p<0.001, Eta²=0.404) is found. There was no significant difference in the pattern of change of bodily pain over time (p=0.207 , Eta2=0.028) and no significant differences between the groups(p=0.500 , Eta2=0.009). NC=patients without complications, MC= patients with minor complications, SC= patients with severe complications.*

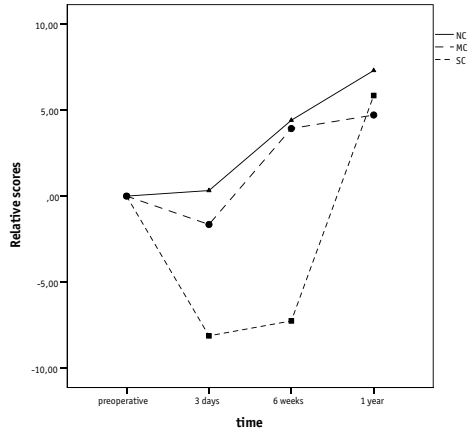

Figure 3E. *General mental health (psychological distress and well-being). A large effect of time ($p<0.001$, $Eta^2=0.225$) is observed. There was a significant difference in the pattern of change of mental health scores over time ($p=0.001$, $Eta2=0.077$), as well as a significant difference between the groups ($p=0.043$, $Eta2=0.042$). NC=patients without complications, MC= patients with minor complications, SC= patients with severe complications.*

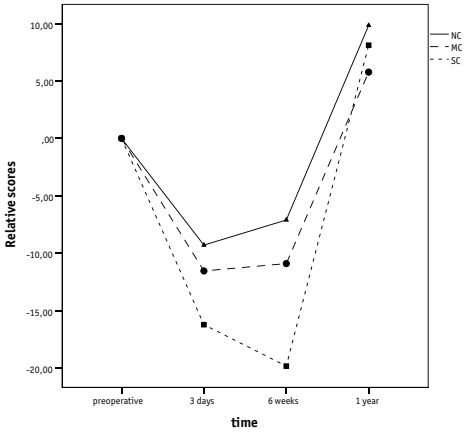

Figure 3F. *limitations in usual role activities because of emotional problems. A large effect of time ($p<0.001$, $Eta^2=0..233$) is observed. There were no significant differences in the pattern of change of role limitations due to personal or emotional problems over time and no significant differences between the groups. NC=patients without complications, MC= patients with minor complications, SC= patients with severe complications.*

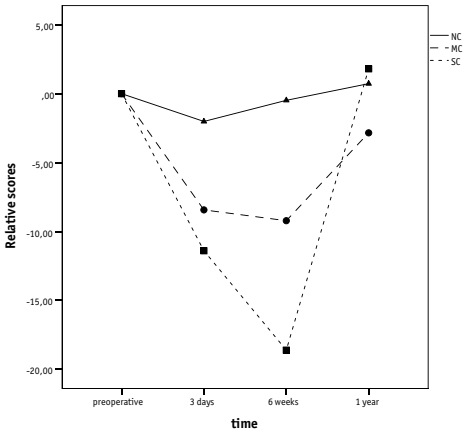

Figure 3G. *Vitality (energy and fatigue). A large effect of time ($p<0.001$, $Eta^2=0.294$) is found. There was a significant difference in the pattern of change of vitality over time ($p<0.001$, $Eta2=0.101$) but no significant differences between the groups ($p=0.052$, $Eta2=0.039$). NC=patients without complications, MC= patients with minor complications, SC= patients with severe complications.*

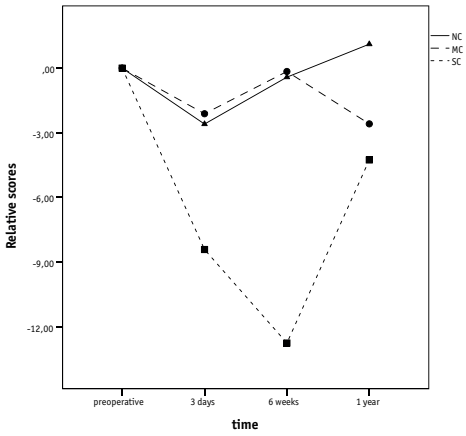

Figure 3H. *General health perception. A moderate effect of time (p=0.002, Eta²=0.096) is observed. There was a significant difference in the pattern of change of general health perception over time(p=0.007, Eta²=0.059), as well as a significant difference between the groups (p=0.011, Eta2=0.059). NC=patients without complications, MC= patients with minor complications, SC= patients with severe complications.*

Discussion

This study is the first to document postoperative health status , anxiety and depressive symptoms following both uncomplicated and complicated colorectal surgery. It showed that colorectal surgery has a measurable effect on depressive symptoms, anxiety and all domains of health status. It further showed that postoperative anxiety and depressive symptoms are comparable in both patients with complicated and uncomplicated postoperative courses. However, patients with a severely complicated postoperative course have a larger postoperative decrease in health status, with the largest effects in the domains of limitations in physical activities and social activities, the general mental health domain, vitality and general health perception. Other consequences of complications we found in this study, such as increased length of stay, more frequent readmissions, reoperations and ICU admissions and increased mortality were all in accordance with other studies[1,2,3,4,5].

Patients after colorectal surgery experience a short term increase in depressive symptoms in the early postoperative period, regardless of the presence of complications. At six weeks postoperatively, these symptoms have already returned to preoperative levels. No other studies have documented depressive symptoms in the perioperative- and postoperative period in colorectal surgery, but a similar pattern is seen following coronary artery bypass grafting[28,29]. With regard to anxiety, all patients experienced a decrease in anxiety levels over time, which is in accordance with prior studies after coronary bypass grafting[29], although there was a tendency for a slower decrease in patients with complications.

The changes in perioperative and postoperative anxiety levels and depressive symptoms were comparable in both patients with complicated and uncomplicated postoperative courses. This is remarkable, since the occurrence of complications did have a notable

effect on physical and mental health status. Possible explanations include insufficient sensitivity to change of the measures to show small differences in anxiety levels and depressive symptoms between the groups and the possibility that anxiety levels and depressive symptoms are much more influenced by other factors (i.e. social support from friends and loved ones, attention of medical personnel, perceived quality of medical care) than by medical events. Unfortunately, literature on the relationship between complications and anxiety and depressive symptoms is scarce. The pre-mentioned studies on depression and anxiety following coronary artery bypass grafting did not investigate the relationship with complications. To our knowledge, the only study to document postoperative anxiety and depression with regard to postoperative complications found that self-reported complications after breast reconstruction were related to higher anxiety levels and more depressive symptoms[10]. These results are conflicting with our results. Possible explanations for this phenomenon are that patients with higher anxiety and depressive levels are more likely to report events as complications or, alternatively, that complications following surgery for breast cancer affect these patients in a different manner than patients undergoing colorectal surgery, while an effect of gender differences in coping with complications, although unlikely, cannot be ruled out.

This study revealed that patients with severe complications following colorectal surgery have a larger postoperative decrease in health status compared to patients with no- or only minor complications. This was most profound at six weeks postoperatively with the largest effects in the domains of limitations in physical activities and social activities, the general mental health domain, vitality and general health perception. Interestingly, all aspects of health status had normalized to preoperative levels at one year postoperatively.

Studies on the effects of complications on health status and quality of life are few, if any. Our present study is the first to document that severe, but not minor complications affect not only physical, but also mental health. This should raise awareness in physicians and aid them in recognizing possible psychological problems in patients with a complicated postoperative course. Although at 6 weeks the effects are notable, at 1 year the adverse effects of the complications on mental health mostly have disappeared. From our present study we do not know how long it takes for the adverse effects to wear out in the first postoperative year. Future studies may further document the evaluation of mental and physical health status following complicated colorectal surgery. In addition, these studies may investigate whether psychological counselling can accelerate recovery of mental health status. To our knowledge, no prospective longitudinal studies on the effects of complications on health status in patients undergoing colorectal surgery have been published, although there are some interesting results from cross-sectional studies that addressed the relationship between complications and health status. These suggest that the impact of complications may last for longer than one year postoperatively. A cross sectional study in colorectal cancer survivors more than five years post-surgery showed that complications of the initial surgical procedure were associated with reduced long term health status[8]. A cross-sectional study evaluating liver recipients more than six months after liver

transplantation showed decreased scores on the MCS subscale of the SF-36 in patients who had experienced complications[30].
Although the results from this study are valuable, there are also some limitations that need to be addressed. As in any questionnaire study, we had a certain amount of missing data. Sometimes patients forgot to or refused to fill out specific items in the questionnaires, or they refused to complete the entire questionnaire. However, the amount of missing data is acceptable for a questionnaire study. Another potential drawback of our study is the mixture of different diseases and different surgical procedures, especially patients with and without cancer and chemotherapy, which may influence the results to a certain extent. Because of the prospective longitudinal nature of the study in a single hospital, the number of patients was rather limited. Therefore, we cannot rule out small effects of complications on anxiety, depressive symptoms, and health status that are not detected by this study due to lack of statistical power. For this reason, we could not investigate effects of individual complications on anxiety, depression and health status. A final remark is to be made concerning the problem that many facets in life may influence anxiety, depressive symptoms, and health status and not all events in the lives of our patients are known to us.

Conclusion

Colorectal surgery has a measurable effect on depressive symptoms, anxiety and all domains of health status. Perioperative and postoperative anxiety levels and depressive symptoms are comparable in both patients with complicated and uncomplicated postoperative courses, whereas patients with severe complications in the postoperative course have a larger decrease in health status, most notably at six weeks postoperatively and most notably in the domains of limitations in physical activities and social activities, the general mental health domain, vitality and general health perception. Further studies may document the impact of specific complications on anxiety, depressive symptoms and health status and investigate the duration of the effects of complications on the domains of health status.

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Chapter 6

Operative treatment of patients with pertrochanteric femoral fractures during duty hours is not associated with higher incidence of complications or higher mortality

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Abstract

This retrospective cohort study was conducted to investigate whether operative treatment of patients with a pertrochanteric femoral fracture during duty hours is associated with an increased risk of complications and higher mortality. During the study period 165 patients were operated during duty hours (DH) and 123 patients were operated during regular working hours (WH). There were no differences in early complications (DH 33% versus WH 33%, p=0.91) or total complications during follow-up (DH 40% versus WH 41%, p=0.91). Both in-hospital mortality (DH 12% versus WH 11%, p=0.97) and mortality after 1 year (DH 29% versus WH 27%, p=0.67) were comparable. Adjustment for possible confounders by multivariate logistic regression analysis revealed no increased risk of complications when patients were operated in duty hours. On the basis of these data, there is no medical reason to postpone operative reduction and fixation in patients with a proximal femoral fracture to regular working hours.

Introduction

Hip fractures are among the most common fractures in the elderly and associated with significant morbidity and mortality. It is the second leading cause for hospitalisation in elderly patients[1]. Annually there are about 17.000 hip fractures in the Netherlands [2] and about 340.000 hip fractures in the United States of America [3]. The number of patients with a hip fracture is expected to increase, due to aging of the population, the treatment of which will probably become a major burden to health care professionals in the future.

An issue that has been the topic of various studies is the timing of surgery in hip fractures, although results of different studies are conflicting [4-10]. Best practice guidelines, however, usually advise to operate within 24 hours following the fracture, since in many large series early operative treatment is associated with lower mortality and fewer postoperative complications [11]. This focus on early treatment puts the pendulum to an increase of operations in duty hours. Kelz *et al*. recently showed that patients in general surgery operated between 4 pm and 11 pm result in a higher number of complications as compared to patients operated during regular working hours[12]. The timing of surgery in hip fractures has long been, and still is, subject of much debate. Recent studies have shown an increased risk of complications in patients admitted or treated during duty hours [13, 14], which may reduce the willingness to perform osteosynthesis for hip fractures outside regular working hours. It remains to be seen whether the results of these studies can be extrapolated to hip fracture surgery. The aim of this retrospective cohort study was to compare outcome in patients operatively treated for pertrochanteric femoral fractures during duty hours (DH) and regular working hours (WH) in terms of mortality, postoperative complications and survival.

Patients and methods

All patients who received operative treatment for pertrochanteric femoral fractures (ICD-10 code S72.1) in our hospital in the years 2000 to 2007 were included in this study.

Our surgical department is part of a teaching hospital, in which 11 surgeons and 12 residents participate. In our hospital, patients with a hip fracture are operated by an experienced general surgeon or a specific trauma surgeon, who have performed >100 operative procedures for hip fractures or by a resident under their direct supervision, depending on the time of day and who is on call. All patients are pre-operatively screened by a cardiologist and/or a pulmonologist, and prepared as necessary in collaboration with the anaesthesiologist. The operating theatre functions on full-scale from 8.00 a.m. until 5.00 p.m from Monday to Friday. Outside these hours, one team is on call for emergency procedures, with a backup team available. Immediately after the operation patients are usually monitored on the post-anaesthesia care unit before they return to the ward. If necessary a medium care or intensive care facility is available for postoperative monitoring. Postoperatively, patients are mobilized with crutches or a walker from the first postoperative day onward. Patients are encouraged to stay out of bed and sit up in a chair, and the patient exercises to train muscle strength in the operated hip and leg under direct supervision of a physiotherapist.

Since 1995 an electronic patient record is used in our hospital, in which all relevant patient data as well as complications are prospectively recorded. Upon admission to the emergency department, a complete history including co-morbidities, premorbid ambulant status and living situation is recorded. Age, sex, comorbidity, American Society of Anesthesiologists (ASA)-classification, time and cause of injury (high energy or low energy trauma), date and hour of diagnosis, free-text description of the diagnosis, as well as the ICD-10 code are routinely recorded in the electronic patient record. Date, starting time and duration of the operation, type of operation both as free-text and code, blood loss, type of implant (for all: Synthes, Bettlach, Switzerland), operating surgeon or surgical trainee, and a detailed description of the operative procedure performed are also routinely recorded. In the electronic medical record the complete postoperative course during admission and after discharge at the outpatient department is also registered, including length of hospital stay and complications. All patient records were reviewed and corrected for registration errors, if necessary. All X-rays were reviewed and fractures were classified using the Arbeitsgemeinschaft für Osteosynthesefragen (AO) / Orthopaedic Trauma Association (OTA)-classification system.

For the prospective registration of complications, we use the standard definition as given by the Association of Surgeons of the Netherlands: "A complication is any condition or event, unfavourable to the patient's health, causing irreversible damage or requiring a change in therapeutic policy"[15, 16]. These complications are prospectively coded according to the Trauma Registry of the American College of Surgeons Committee on Trauma (TRACS)[17]. Besides this, a free-text description of the complication is also recorded. The TRACS system was specifically designed as a complication list to record

the morbidity in trauma patients. Since prospective registration of complications is known to be often incomplete and inconsistent[18] all patient records were fully reviewed for non-registered complications and the coding and free-text description of registered complications were checked. Early postoperative complications were defined as occurring either while the patient was still admitted or occurring within 30 days after surgery if the patient had been discharged. Late complications were defined as any major adverse event that occurred in the year following the operation, with a clear relation to the hip fracture or osteosynthesis. Total complications combines both early and late complications. In-hospital mortality was defined as death during hospital admission or death within 30 days after surgery if the patient had been discharged. Since this is a retrospective study design, no actual patient follow-up for the specific purpose of this study took place. Our hospital protocol dictates that patients with a hip fracture should be followed for 1 year after surgery. When the protocol was violated and postoperative follow-up was less than 1 year, the general practitioner of the patient was telephoned to inquire whether the patient was still alive and whether the patient had visited any doctor since discharge from our outpatient department to ensure no complications would be missed. Patients were excluded from analysis if follow-up was less than 30 days and the general practitioner could not provide reliable information on the patient or when the patient nor the general practitioner could be traced.
An operative procedure was regarded as performed during regular working hours if it was started between 8.00 a.m. and 05.00 p.m. from Monday to Friday. Outside these hours the procedure was recorded as performed during duty hours.

Statistical analysis

All data were analysed using the Statistical Package for the Social Sciences (SPSS) version 16.0. Differences between groups were analysed by Chi-square test for k×k tables. Nonparametric data were analysed using the Mann-Whitney U-test whereas the Student's t-test was used for continuous variables with a normal distribution. Kaplan-Meier analysis was used for survival times and survival was compared using the log rank test. Multivariate logistic regression analysis was used to calculate the odds ratio (OR) of in-hospital and 1-year mortality, early complications and total complications for patients operated in duty hours, compared to patients operated during regular working hours. To adjust for confounding, we entered the variables of age, sex, presence of dementia, presence of diabetes, cardiac comorbidity, pulmonary comorbidity, premorbid ambulant status, premorbid living situation, type of fracture, operation performed by trauma surgeon, time from diagnosis to surgery and ASA-classification one by one. In the final model, all confounders were included that changed the regression coefficient for duty hours by 10% or more, independent of significance. Finally, a post-hoc power analysis was performed to determine the difference in mortality- and complication rate that our sample size should be large enough to detect.

Results

During the study period 298 pertrochanteric femoral fractures were operatively treated. During duty hours, 165 patients were operated on, with a median starting time of 7 pm (5 pm to 10 pm) from Monday to Friday, and a median of 2 pm (9 am to 10 pm) during weekends. During working hours 123 patients were operated on, with the operation starting at a median of 2 pm (8 am to 4 pm)."None of the patients had simultaneous bilateral fractures. Ten patients had follow-up less than 30 days and were excluded from analysis (4 operated during regular working hours and 6 operated during duty hours, p=0.87, Chi-square test). Patient characteristics are shown in Table 1. Both groups were comparable with respect to age, ASA-classification, comorbidity, high energy trauma and fracture type. In the DH-group there were more patients living in a medical care facility. There was a trend towards more female patients and more patients using a walking-aid in the WH-group, but this difference was not statistically significant.

Table 2 shows the operative characteristics, complications and mortality for both groups. They were comparable regarding the type of implant, blood loss and length of hospital stay. During regular working hours, the procedure was more frequently performed by a trauma surgeon. Duration of the operation was similar in both groups. The time from diagnosis to operation more frequently exceeded both 24 hours and 48 hours in patients operated during working hours. There was no difference between the groups with respect to early or overall complication rate. In patients with complications, the median number of complications was 1 (interquartile range 1-2) in patients operated during working hours and 1 (interquartile range 1-1.25) in patients operated during duty hours (p=0.10, Mann-Whitney U-test). Of all patients operated during regular working hours 16 (13%) needed one or more reoperations compared to 21(13%) patients operated during duty hours. In these patients, a median of 1 reoperation (interquartile range 1-1.75) was necessary in WH compared to a median of 1 reoperation (interquartile range 1-5.5) in DH (p=0.15, Mann-Whitney U-test). In-hospital mortality and 1-year mortality during follow-up were similar in both groups. Duration of follow-up in patients surviving both hospital admission and more than 30 days was longer for the group operated in working hours (median 757 days; interquartile range 189-1362) than the group operated in duty hours (median 437 days; interquartile range 145-1013), (p=0.017, Mann-Whitney U-test), but the median time to in-hospital death was not statistically different (WH-group 21 days - interquartile range 5.5-25 *versus* DH-group 10 days - interquartile range 6-23; p=0.69, Mann-Whitney U-test).

Table 1. *Baseline patient characteristics*

	Working Hours		Duty Hours		*p*-value*
		%		%	
Patients (*n*)	123	43	165	57	
Age (years±SD)	79±13		79±12		0.94
Female (*n*)	101	82	121	73	0.08
ASA					
I	16	13	12	7	0.10
II	51	42	76	46	0.44
III	53	43	71	43	0.99
IV	3	2	6	4	0.56
Cardiovascular comorbidity (*n*)	37	30	49	30	0.94
Pulmonary comorbidity (*n*)	20	16	28	17	0.87
Diabetes mellitus (*n*)	17	14	24	15	0.86
Dementia (*n*)	16	13	20	12	0.82
High energy trauma (*n*)	6	5	3	2	0.14
Delirium on admission (*n*)	0	0.0	1	0.6	0.39
Premorbid ambulant status					
No walking aid	34	27	59	36	0.15
Walking stick or walker	88	72	102	62	0.08
Wheelchair or bed dependent	1	0.8	4	2	0.31
Premorbid living situation					
Independent	76	62	89	54	0.18
Social care facility	40	33	53	32	0.94
Medical care facility	7	6	23	14	0.02
Fracture classification (AO/OTA; *n*)					
31-A1	48	39	71	43	0.49
31-A2	56	46	64	39	0.25
31-A3	19	15	30	18	0.54
Pathologic fracture (*n*)	2	1.6	2	1.2	0.77

*All p-values were calculated using the chi-square test, with the exception of age, for which the student t-test was used.

Table 2. *Operative characteristics and outcome*

	Working Hours		Duty Hours		
		%		%	P*
Number of patients (n)	123	100	165	100	-
Time to operation (n)					
<24 hours	66	54	122	74	0.0003
24-48 hours	40	33	36	22	0.0415
>48 hours	17	14	7	4	0.0036
Type of osteosynthesis (n)					
dynamic hip screw	54	44	82	50	0.33
pertrochanteric femoral nail	68	55	82	50	0.35
other	1	0.8	1	0.6	0.83
Starting hour of the operation (h)					
Weekdays	14 (8-16)**		19 (17-22)**		-
Weekend days	-		14 (9-22)**		-
Operation time (min)	67 (52-87)***	-	62 (49-67)***	-	0.07
Blood loss (ml)	100 (100-200)***		100 (50-200)***	-	0.52
Operation by trauma surgeon (n)	89	72	84	51	<0.001
Length of hospital stay (days)	11 (8-19)***	-	11 (6-18)***	-	0.49
Total complications (n)	50	41	66	40	0.91
Early complications (n)	41	33	54	33	0.91
In-hospital mortality (n)	14	11	19	12	0.97
One-year mortality (n)	33	27	48	29	0.67

* p-values calculated using the Chi-square test, unless stated otherwise. ** range is provided between parenthese *** median and interquartile range (between parentheses) are provided, p-values calculated using Mann-WhitneyU-test

Table 3. *Logistic regression analysis*

Patients operated during duty hours (n=165)	Univariate model			Multivariate model*		
	B	p-value	OR (95% CI)	B	p-value	OR (95% CI)
In-hospital mortality	0.01	0.97	1.00 (0.49-2.10)	0.11	0.77	1.12 (0.53-2.40)
One year mortality	0.11	0.67	1.19 (0.66-1.89)	0.32	0.26	1.37 (0.79-2.39)
Early complications	-0.03	0.91	0.97 (0.59-1.60)			
Total complications	-0.27	0.91	0.97 (0.61-1.57)			

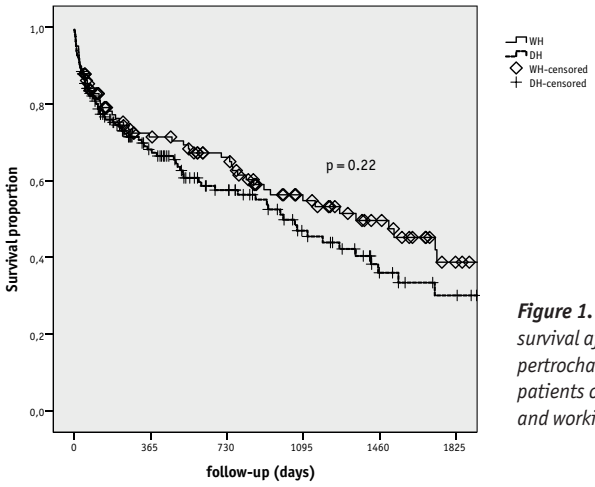

Figure 1. *Kaplan-Meier curve showing survival after operative treatment for pertrochanteric fractures comparing patients operated during duty hours (DH) and working hours (WH)*

In the univariate model the odds ratio (OR) for early complications for patients operated during duty hours was 0.97 (95% CI 0.59-1.60). The OR for total complications was also 0.97 (95% CI 0.61-1.57). In the univariate model the OR for in-hospital mortality for patients operated during duty hours was 1.0 (95% CI 0.49-2.10). The OR for 1-year mortality for patients operated during duty hours was 1.19 (95% CI 0.66-1.89). Multivariate logistic regression analysis revealed no confounding effect of age, gender, ASA-classification, cardiac comorbidity, pulmonary comorbidity, diabetes, dementia, premorbid ambulant status, premorbid living situation, type of fracture, time from diagnosis to surgery and whether or not the operation was performed by a trauma surgeon on the development of both early and late complications. None of these variables changed the regression coefficient for duty hours by 10% or more. After adjustment for time to operation, patients operated during duty hours had a non-significant small higher risk of in-hospital death (OR 1.12; 95% CI 0.53-2.40) as well as a non-significant association with higher risk of death after 1 year (OR 1.37; 95% CI 0.79-2.39). These results are shown in Table 3.

There were no differences in surgery related complications between both groups. The incidence of cardiac, neurologic, gastro-intestinal and infectious complications was also similar. In patients operated during regular working hours there were more pulmonary complications (WH 10 *versus* DH 4, p=0.03, chi^2-test). Kaplan-Meier survival analysis (Figure 1) showed no difference in survival between both groups (p=0.22, log rank test).

A post-hoc power analysis showed that with a power of 0.80 and a significance level of 0.05, our sample size would be large enough to detect an increase from 11% inhospital mortality to 25% in hospital mortality. With regard to complications, our sample size would be large enough to detect an increase from 33% early complications to 50% early complications.

Discussion

This study is the first to investigate the relation between time of day of the operative procedure and the incidence of complications and mortality in patients with pertrochanteric fractures. It shows that both the risk of complications and mortality during duty hours are similar to those operated during working hours. Analysis of the relative incidence of complications showed that little difference exists between both groups with regard to the frequency of the various complications. Only pulmonary complications were more frequently observed in patients operated during regular working hours, but a relationship with prolonged time from diagnosis to surgery was not found. Interestingly, there was no difference in surgery related complications which suggests that the performance of surgeons during working and duty hours is comparable. There also was no difference in complication rate or mortality between patients operated by trauma surgeons or general surgeons (data not shown). The similar incidence of non-surgery related complications reflects a comparable level of perioperative care during regular working and duty hours. Long term survival was comparable in both groups, although from 1 year onward a trend towards increased mortality was seen in patients operated during duty hours. This probably reflects the somewhat larger proportion of ASA II and IV patients operated during duty hours. The higher proportion of males in the group of patients operated during duty hours may also be of importance. The study includes many old-aged patients and since men have shorter life-expectancy, a higher proportion of men may contribute to decreased survival in this group of patients.

An effect of time of day of operative hip fracture treatment on the outcome in terms of complications and mortality is imaginable since it has been found in other fields of health care. In a study on general and vascular surgical procedures, a 1.6 times higher risk of complications, but not mortality, was found in patients operated outside regular working hours[12]. Likewise, admission to the ICU during weekends has been associated with a higher mortality[14] and outcome following primary angioplasty for acute myocardial angioplasty is worse for procedures performed during duty and weekend hours[13,23].

Factors underlying an increased risk of complications from surgery outside working hours can both be patient and health care provider related. From a physiological point of view, patient related factors are less likely to contribute to this adverse effect than factors related to the medical staff. This hypothesis is supported by several non-medical studies that have found an association between time of day and the risk of vocational accidents and changes in driving performances[19-22]. As other technical skills, surgery is probably influenced by the same physiological processes increasing the risk for technical failures in the evening and night. Differences in knowledge and expertise of the medical staff might also be responsible for differences in outcome of patient care. Our present study however, does not show any effect of the time of day in patients operated for hip fractures in our hospital. Several explanations for this phenomenon are possible. Firstly, it is known that early operative treatment of hip fractures prevents complications[6-10]. The benefit of early surgery may outweigh the risk

of complications in emergent or semi-emergent procedures. Moreover, the complexity of the operative procedure and postoperative care of a hip fracture may be lower than that of vascular surgery[12], angioplasty for myocardial infarction[13,23] or treatment of severely ill patients in the ICU[14]. It is likely that the organization of care during duty hours is more important than the time of day when surgery is performed per se. The level of care and facilities in ICU-patients or patients needing coronary angioplasty probably by far exceed that needed for patients with pertrochanteric hip fractures. Thus the difference between the level of care during duty hours and regular working hours will be small, if at all existent. In pertrochanteric fractures, good clinical practice requires the operation to be performed as soon as possible, under the best possible circumstances. In the pre-operative phase this requires medical optimization of the patient by the cardiologist, pulmonologist and anesthesiologist in close cooperation. In the operative phase a capable anesthesiologist, a skilled (trauma) surgeon as well as well-trained nursing staff are essential to perform the osteosynthesis. Postoperative care must encompass a post-anesthesia care unit and availability of medium or intensive care facilities to monitor patients if needed. Only if such facilities are not available outside regular working hours, or if patient optimization requires more time, surgery may be delayed.

Although the results are both valid and valuable, this study has some limitations. Since we are not properly informed about the functional outcome, our study cannot rule out differences in functional recovery in patients operated during duty hours as compared to patients operated during working hours. Besides, due to its observational and non-randomized design, the study must be categorized as level 2b. However, a randomized study would be unethical, since it requires the operation to be delayed in some patients, which is associated with a higher risk of complications[8-10] and mortality[6, 11]. Another confounding factor might be that the more healthy patients with simple fractures have been operated immediately, whereas surgery in patients with comorbidities or complex fractures was postponed and performed the following day during regular working hours. However, adjustment for time from diagnosis to surgery, fracture classification and other patient characteristics by logistic regression did not change the results of the study in any way. A final factor that needs consideration is the sample size. Since our study population contained only 288 patients, it is underpowered to rule out smaller, but possibly clinically relevant differences. However, since our study shows almost identical complication and mortality rates in patients operated during duty hours as compared to those operated during working hours it is unlikely that a study with larger numbers will reveal clinically relevant differences in complication- and mortality rates. A major strength of this study is the completeness and reliability of all data due to prospective recording in a structured electronic medical record, which in our hospital is in use since 1995. Moreover, the accuracy of all data was checked and – if necessary - corrected after agreement by all authors. Another major advantage of this observational study is that it reflects common practice very well, in this case from an average European teaching hospital.

Conclusion

This study lends no support to the proposition that operative reduction and fixation in patients with a proximal femoral fracture should be postponed to regular working hours to reduce morbidity and mortality. Especially healthy patients (ASA-class I-II) should be operated without delay. In patients with significant comorbidities the operation should be postponed until they are properly and optimally prepared for operation. Of course, if essential hospital facilities are not available during duty hours, it is wise to perform the operation during working hours. In all other situations, surgery for pertrochanteric femur fractures during duty hours seems safe.

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Chapter 7

Appendectomy by residents is safe and not associated with a higher incidence of complications. A retrospective cohort study

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Abstract

Objective

The purpose of this retrospective cohort study was to investigate whether current practice where residents perform appendectomies affects quality of care. Therefore, we investigated whether there was a difference in incidence of complications and mortality in appendectomies performed by surgeons (S), supervised residents (SR), or unsupervised residents (UR).

Introduction

Appendicitis is among the most frequent conditions requiring urgent surgery. Admittance and surgery are often managed by residents. Recent studies have shown that laparoscopic appendectomy can be safely performed by residents. It is not known whether these results are applicable on appendectomies in general.

Methods:

All patients undergoing appendectomy in our hospital between January 1, 2000, and December 31, 2009, were included in the analysis. Patients undergoing appendectomy by surgeons, supervised residents, and unsupervised residents were compared. Primary endpoints were complications and mortality.

Results

During the study period, 1538 patients were operated. The risk of complications (S: 20% vs SR: 17% vs UR: 16%; P = 0.209, S vs SR; P =0.149, S vs UR; and P=0.872, SR vs UR) and mortality (S: 0.3% vs SR: 0.2% vs UR: 0.4%, P = 1.000 for all comparisons) were similar in all groups. In the multivariate model, the odds ratio for complications in the group operated by supervised residents was 0.84 (95% CI: 0.58–1.22, P = 0.357) versus 0.81 (95% CI: 0.55–1.18, P = 0.265) in the unsupervised residents' group.

Conclusion

Current practice where residents perform appendectomies either unsupervised or supervised by an experienced surgeon should not be discouraged. We found that it is safe and does not lead to more complications or negatively affect quality of care.

Introduction

With around 16000 procedures per year in The Netherlands[1] and more than 320 000 in the United States of America[2], appendectomy is one of the most frequently performed acute operations in surgery. The admittance of these patients and subsequent operation is often managed by surgical residents, either unsupervised or supervised by a surgeon. Although in the past they were more likely to perform open appendectomies, recent studies have shown that there is a shift towards more laparoscopic appendectomies by residents[3,4]. Other studies show that unsupervised laparoscopic appendectomy by residents is safe and time effective[5,6] and that operative time and complications were reduced with increasing experience of the resident[7].

The relation between the level of resident education and the quality of medical care has received significant amount of attention over the past years, both from professionals as from the media. Especially in the United States of America there have been concerns that the implementation of resident work hour restrictions would reduce the number of operations by residents and thus affect the quality of care they would deliver. Recent studies relating to this concern have shown conflicting results[8,9,10,11,12]. In addition, numerous studies have been carried out comparing the experience of surgeons versus surgical residents in terms of complications and mortality rates[9,13,14,15]. Some of these studies show that physician inexperience early in the academic year does not affect patients in terms of postoperative mortality and morbidity[13]. Furthermore, they show that clinical outcomes do not deteriorate with change in the level of resident supervision in the operating room[16].

The appendectomy is an operation which is traditionally one of the first and most common procedures performed by residents without supervision. However, whether appendectomies performed by residents are related to a higher incidence of complications, has never been studied. Therefore, the aim of this retrospective cohort study was to compare outcomes in patients operatively treated for appendicitis by either a surgeon (S), a resident supervised by a surgeon (SR) or an unsupervised residents (UR) in terms of postoperative complications and mortality.

Methods

All patients undergoing appendectomy for appendicitis between January 1st 2000 and December 31st 2009 in our hospital were included in the analysis. Patients undergoing appendectomies for other reasons were excluded. Our surgical department is part of a teaching hospital, in which 11 surgeons and 12 residents participate. Appendectomies are performed by surgeons (S), residents under supervision of a surgeon (SR) or unsupervised residents (UR). In this study, an 'unsupervised resident' is defined as a resident acting as the primary operating doctor assisted by either another resident, a scrub nurse or a medical student, as stated in the electronic medical record. In our hospital, no specific rules apply to define if a resident is qualified to perform an appendectomy without supervision. The resident is allowed to perform the operation without supervision when the surgeon on call considers the resident capable of doing so. The level of resident training generally is not an issue in making this decision although usually the more experienced residents perform this operation unsupervised. Being a teaching hospital, we prefer to have the residents perform the operations, either unsupervised or supervised by a qualified surgeon. The choice for open or laparoscopic appendectomy is discussed between the resident and surgeon, although in general we choose a laparoscopic approach unless there is clear radiologic evidence for appendicitis. In our hospital the decision to add this imaging (e.g. ultrasound or CT) to the general work-up is based on clinical grounds. If these tests are inconclusive but there is still a high suspicion of appendicitis a diagnostic laparoscopy is performed. Generally, we intend to perform a laparoscopic appendectomy unless there are contra-indications. The decision to convert from laparoscopic to open appendectomy is made during the operation. When the resident performs the operation unsupervised, this decision is usually made after consulting the surgeon on call.

Since 1995 an electronic patient record (EPR) is used in our hospital, in which all relevant patient data as well as complications are prospectively recorded. Upon admission to the emergency department, a complete history including duration of symptoms and co-morbidities, as well as physical examination and laboratory investigations are recorded. Other parameters including age, sex, American Society of Anesthesiologists (ASA)-classification, as well as the ICD-10 code[17] are also documented in the electronic patient record. In addition, the date, starting time and duration of the operation, type of operation (laparoscopic, gridiron incision, laparotomy or laparoscopic converted to open surgery) both as free-text and code, operating surgeon or surgical resident and a detailed description of the operative procedure performed are also consistently recorded. In the EPR the complete postoperative course during admission and after discharge at the outpatient department, is also registered, including length of hospital stay and complications.

For the prospective registration of complications, we use the standard definition as given by the Association of Surgeons of the Netherlands (ASN): "A complication is any condition or event, unfavourable to the patient's health, causing irreversible damage or requiring a change in therapeutic policy"[18]. Since our hospital is a certified trauma centre, all complications are prospectively coded according to the Trauma Registry of

the American College of Surgeons Committee on Trauma[19]. The list explicitly defines complications and uses four-digit-codes. Although this list was developed for the trauma population, its design is broad and encompasses practically all complications applicable to general surgery. Besides this, a free-text description of the complication is also recorded. Complications in our surgical department are documented in the EPR. It is easily accessible for all doctors through the hospital and outpatient clinic. All complications are discussed in our daily surgical conference. Since prospective registration of complications is known to be often incomplete and inconsistent[20], we fully reviewed all patient records for non-registered complications. Furthermore, we checked the coding and free-text description of registered complications. In this study, we used the definition of a complication of the ASN. Since this definition defines no time frame for complications, for the purpose of this study we included in the analysis any complication that occurred during follow up, either within 30 days of the operation or during patient follow-up if the complication had a clear relation to the appendectomy. We defined in-hospital mortality as death of the patient during admission or within 30 days after discharge from hospital. Since this is a retrospective study design, no actual patient follow-up for the specific purpose of this study took place. Duration of follow-up was defined as the number of days from the operation until the last visit to the hospital concerning this operation. All patients receive an appointment for the outpatient department upon discharge from the hospital. This appointment is usually scheduled around 7 to 14 days after surgery. However, patients who did not present to the first appointment on the outpatient department, and thus had follow up of less than 7 days following discharge, were considered lost to follow up since the outpatient complications could not be determined.

Statistical analysis

All data were analysed using the Statistical Package for the Social Sciences (SPSS) version 18.0. Differences between groups were analysed by Fisher's exact test for 2×2 tables, by Chi-Square test or by the One Way Anova-test. The Mann-Whitney U test was used for non-parametric data. Multivariate logistic regression analysis was used to calculate the odds ratio (OR) of all complications, wound infections and intra-abdominal abscesses for patients operated by UR compared to patients operated by S, and for patients operated by SR compared to patients operated by S. To adjust for confounding, we entered the variables of age, sex, ASA-classification, operating time, time from diagnosis to surgery, type of operation and presence of perforation. In the multivariate model all variables that on clinical grounds could potentially act as confounders were included, regardless of effect size or statistical significance. Power analysis was performed prior to data acquisition. We decided that an increase of complications from a baseline complication rate of 15% to 25% would be the minimum difference we would consider clinically significant. With a power of 0.80 and an alpha of 0.05 we would need at least 270 patients in each group to detect this increase of complications in patients operated by SR as compared to UR.

Results

Study population

During the study period, a total of 1538 patients underwent appendectomy, of whom 352 (22.9%) were operated by S, 597 (38.9%) by SR and 589 (38.2%) by UR. Of these, 87 (5.7%) patients were excluded from the analysis because of a duration of follow up of less than seven days after discharge. Nineteen (5.4%) of these patients were operated by S, 40 (7.2%) by SR and 28 (5.0%) by UR ($p = 0.488$ S vs SR, $p = 0.759$ S vs UR and $p = 0.172$ SR vs UR). Of the remaining 1451 patients, S operated upon 333 (22.9%), SR upon 557 (38.4%) and UR upon 561 (38.7%).

Study outcome

In table 1 the baseline patient characteristics are shown. Both groups were comparable regarding age, sex and duration of symptoms. In the group operated by S, more patients had ASA-classification II. SR and UR operated more patients with ASA-classification I.

***Table 1**. Baseline patient characteristics*

	Surgeon (S) (%)	**Supervised Resident (SR)** (%)	**Unsupervised Resident (UR)** (%)	**p-value**		
				S vs SR	S vs UR	SR vs UR
Patients (n)	333	557	561			
Age (mean±SD)*	31.9 (19.5)	30.8 (18.2)	29.8 (17.3)	1.000	0.327	1.000
Male sex (n)	156 (47)	293 (53)	285 (51)	0.111	0.269	0.550
Duration of symptoms in days (median, min-max)**	1 (1-17)	1 (1-45)	1 (1-14)	0.728	0.536	0.265
ASA class (n)***				0.006	0.001	0.746
I	243 (73)	457 (82)	469 (84)			
II	73 (22)	83 (15)	78 (14)			
III	15 (4)	17 (3)	14 (2)			
IV	2 (1)	0	0			
Follow-up in days (median, IQR)**	10 (7-25)	10 (7-21)	10 (7-18)	0.184	0.045	0.443

All p-values calculated by Fisher's exact test, unless stated otherwise; * One way ANOVA; ** Mann-Whitney U-test ; *** Chi-square test

In table 2 the operative characteristics are shown. There were no differences regarding time to operation. S had shorter operation times compared to SR and UR. S performed significantly more laparoscopic appendectomies than SR, but not than UR. Appendectomies by laparotomy were also more frequently performed by S, whereas SR and UR conducted more gridiron incisions and open appendectomies (through a gridiron incision) after conversion from laparoscopy. S removed more appendices that macroscopically appeared normal. Nevertheless, the incidence of perforated appendicitis and periappendicular mass was comparable in all three groups. Patients operated by S and SR more often had pus in the abdominal cavity and were thus more frequently treated with a therapeutic antibiotic regimen. In table 3 the outcomes after operation are shown. The total hospital stay was longer in patients operated by SR compared to UR. There were no differences between the three groups regarding the number of patients who were readmitted. The number of patients with complications, the number of complications per patient, the incidence of intra-abdominal abscesses, the incidence of wound infections and the number of patients with reoperations was similar in all three groups. Infectious complications make up for almost half (8%) of the total percentage of complications in each group (S 20%, SR 17%, UR 16%). Other complications include - among others – postoperative ileus, urinary tract infection, urinary retention and sepsis. Of the total of 1451 patients a total of only 4 patients died during the study period. Therefore thirty-day mortality was comparable in all three groups.

In table 4 the odds ratio's for complications in patients operated by SR and UR, as compared to S, are shown. The risk of complications was similar in all groups both in the univariate model as well as in the multivariate model, after adjusting for age, sex, ASA-classification, operating time, time from diagnosis to surgery, type of operation and presence of perforation.

This was true when using "all complications" as well as "wound infections" and "intra-abdominal abscesses" as the dependent variable.

Table 2. *Operative characteristics*

	Surgeon (S) (%)	Supervised Resident (SR) (%)	Unsupervised Resident (UR) (%)	p-value		
				S vs SR	S vs UR	SR vs UR
Patients (n)	333	557	561			
Time to operation in hours (mean, ±SD)*	7.5 (±8.2)	6.9 (±6.4)	6.9 (±5.8)	0.490	0.588	1.000
Time of operation in minutes (mean, ±SD)*	46.7 (±17.1)	49.5 (±18.7)	50.0 (±18.3)	0.072	0.019	1.000
Type of operation						
Open appendectomy (n) (RLQ)	56 (17)	147 (26)	134 (24)	0.001	0.014	0.336
Appendectomy by laparotomy (n)	27 (8)	24 (4)	9 (1)	0.025	<0.001	0.008
Laparoscopic appendectomy	176 (53)	221 (40)	273 (49)	<0.001	0.240	0.003
Open appendectomy (RLQ) after conversion (n)	57 (17)	136 (24)	124 (22)	0.012	0.085	0.396
Laparotomy after conversion (n)	16 (5)	29 (5)	21 (4)	0.875	0.488	0.250
Other (n)	1 (0)	0	0	0.374	0.372	1.000
Peroperative clinical diagnosis						
No appendicitis (n)	33 (10)	33 (6)	27 (5)	0.034	0.005	0.429
Phlegmonous appendicitis (n)	182 (55)	327 (59)	366 (65)	0.263	0.002	0.027
Gangrenous/necrotic appendicitis (n)	32 (10)	40 (7)	38 (7)	0.206	0.156	0.815
Perforated appendicitis (n)	71 (21)	138 (25)	116 (21)	0.253	0.865	0.116
Periappendicular mass (n)	15 (4)	19 (3)	14 (2)	0.471	0.119	0.383
Peritonitis						
None (n)	194 (58)	326 (59)	360 (64)	0.944	0.087	0.057
Free Fluid (n)	29 (9)	45 (8)	54 (10)	0.802	0.721	0.400
Pus (n)	110 (33)	186 (33)	147 (26)	0.941	0.032	0.009
Antibiotic treatment						
Prophylactic (n)	201 (60)	330 (59)	379 (68)	0.778	0.030	0.004
Therapeutic (n)	132 (40)	227 (41)	182 (32)	0.778	0.030	0.004

All p-values calculated by Fisher's exact test, unless stated otherwise; * One way ANOVA

***Table 3**. Outcomes after operation*

	Surgeon (S) (%)	Supervised Resident (SR) (%)	Unsupervised Resident (UR) (%)	p-value		
	333	557	561	S vs SR	S vs UR	SR vs UR
Total hospital stay in days (median, min-max)*	4 (1-89)	4 (1-80)	4 (1-59)	0.538	0.077	0.003
Patients readmitted (n)	30 (9)	41 (5)	35 (6)	0.375	0.143	0.478
Patients with complications (n)	68 (20)	94 (17)	92 (16)	0.209	0.149	0.872
Number of complications per patient (median, min-max)*	0 (0-5)	0 (0-7)	0 (0-6)	0.178	0.085	0.686
Patients with an intra-abdominal abscess (n)	17 (5)	24 (4)	24 (4)	0.622	0.621	1.000
Patients with a wound-infection (n)	10 (3)	20 (4)	24 (4)	0.705	0.371	0.645
Patients with reoperations (n)	25 (8)	37 (7)	31 (6)	0.683	0.255	0.455
Number of operations per patient (median, min-max)*	1 (1-4)	1 (1-7)	1 (1-5)	0.665	0.255	0.428
Inhospital mortality (n)	1 (0)	1 (0)	2 (0)	1.000	1.000	1.000

All p-values calculated by Fisher's exact test, unless stated otherwise; * Mann-Whitney U-test

***Table 4**. Logistic regression analysis. OR for complications as compared to operation performed by surgeon. Univariate and multivariate model.*

	Univariate model			Multivariate model		
	OR	95% CI	p-value	OR	95% CI	p-value
Risk of complications when operated by SR	0.80	0.57-1.13	0.21	0.84	0.58-1.22	0.36
Risk of complications when operated by UR	0.78	0.55-1.10	0.15	0.81	0.55-1.18	0.27
Risk of wound infection when operated by SR	1.28	0.60-2.76	0.52	1.15	0.51-2.61	0.74
Risk of wound infection when operated by UR	1.48	0.70-3.10	0.30	1.26	0.56-2.83	0.57
Risk of intra-abdominal abscess when operated by SR	0.85	0.45-1.60	0.61	0.86	0.44-1.68	0.66
Risk of intra-abdominal abscess when operated by UR	0.85	0.45-1.61	0.63	0.78	0.39-1.55	0.47

Adjusted for age, sex, ASA class, operating time, time from diagnosis to surgery, type of operation and presence of perforation.

Discussion

In this study, we examined the incidence of complications after appendectomy for appendicitis by either surgeons, residents supervised by surgeons and unsupervised residents. We found no evidence that patients operated by (un)supervised residents have a higher risk of complications. The appendectomy is one of the first operations which is performed by residents without supervision. We believe that in current practice the residential status as such should be no impediment in allowing residents to conduct this operation alone.

The finding that there is no higher incidence of complications after operations performed by surgeons compared to residents is in accordance with other studies on this subject. Acun et al for example showed that there is no difference in incidence of complications between general surgery residents and attending surgeons in near-total thyroidectomies[21]. Emre et al found similar results for total thyroidectomies[22]. These studies were performed in a prospective fashion and comprise smaller number of patients compared to our study. In a study performed by Mehall et al, results of laparoscopic colectomy, including complications, were similar between supervised residents and attending surgeons[23]. Of course, both the near-total thyroidectomy and laparoscopic colectomy are more advanced operations which are technically more demanding. Nevertheless, these studies are in concordance with our findings that operations performed by (supervised) residents do not lead to more complications. Earlier, multiple studies have shown that laparoscopic appendectomy by residents is safe[5,6,7,16]. Apparently, resident education does not conflict with patient safety nor is quality of care at risk.

Another finding of our study is that surgeons perform more laparoscopic appendectomies and fewer conversions, suggesting that with more experience in laparoscopy, more appendectomies are successfully completed laparoscopically. Recent literature[5,24,25] shows conflicting results on this subject. These studies, however, comprise smaller number of patients compared to our study. Bencini et al stated that residents had lower conversion rates compared to surgeons[24]. Tata et al and Wong et al showed no difference in conversion rates between residents and surgeons[5,25]. However, Wong et al did show that consultant surgeons had significantly shorter operating times which is in concordance with our results. Moreover, they showed that senior surgical residents also had shorter operating times compared to junior residents[5]. This finding is supported by other recent literature[7,25]. In other laparoscopic procedures it also has been shown that with increased experience operating time decreases. Nevertheless, there are no differences in conversion rates[23].

We recognize that our study has some limitations. First, it is observational, non-randomised and retrospective in design. Residents with different years of experience were used for comparison with surgeons with a variable degree of experience as well. The differences in experience has not been accounted for. It is not unlikely that several other confounding factors may have influenced our results. One of the confounding factors might be that the more severely ill patients with perforated appendicitis would

be operated by surgeons and not by residents. When looking at both the patients (table 1) and operative (table 2) characteristics, although there is a difference in patients with an ASA-I or -II classification between the three groups, there are no differences with regard to gangrenous or perforated appendicitis. Furthermore, in the multiple regression analysis we have not found a confounding effect of age, sex, ASA class, operating time, time from diagnosis to surgery, type of operation and presence of perforation. Of course, it is possible that in difficult cases a surgeon was called upon by a up to then unsupervised resident. He would have ended the operation as a resident under supervision when the surgeon came to his aid. This may have increased the number of difficult cases in the SR group. Although this may be true, the comparable incidence of gangrenous or perforated appendicitis in all groups shows that current practice of residents operating without supervision is safe when they can rely on adequate and fast backup by a qualified surgeon. Moreover, unsupervised residents obviously know their limitations and ask for help when the operation gets too difficult. Even though all data and complications were registered prospectively, they were not specifically gathered for this study. Nonetheless, our group has a long history registering all complications in our complication database. All complications are discussed in our daily surgical conference and are – when necessary – corrected for errors. Moreover, a study performed by our group showed that ninety percent of all complications in laparoscopic cholecystectomy were accurately recorded in our EPR[20]. Finally, all medical records were checked for completeness of data and if necessary corrected after agreement by the authors (Graat and Bosma). A final advantage of this observational study is that it reflects common practice in an average European teaching hospital.

Conclusion

Current practice where residents perform appendectomies either unsupervised or supervised by an experienced surgeon should not be discouraged. We found that it is safe, does not lead to more complications nor negatively affects quality of care.

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Chapter 8

Summary and future implications

Summary

This thesis describes the results of several retrospective and prospective observational studies on the impact of complications in surgical patients and the use of complications as outcome parameters.

In *Chapter 1* an introduction is given, explaining the concept of quality of care and it's assessment by structure, process and outcome measures. The role of complications in surgery as outcome measures as well as the registration and classification of complications is discussed. The concepts of Quality of life (QoL), Health status (HS) and anxiety and depressive symptoms are discussed shortly.
In *Chapter 2* a study describing the consequences of 3418 prospectively recorded complications in a cohort of 2033 patients is presented. The complications were classified according to Clavien's system and the consequences of the complications were recorded. Of all complications, 33% were grade I, 26% were grade IIa, 34% were grade IIb, 5% were grade III, and 3% were grade IV. Interestingly, grade I complications often had significant consequences for the patients. This is best illustrated by the finding that 22% of all readmissions were due to grade I complications. Complications that were recorded by similar descriptions showed a large degree of variation in severity. Wound infections, which are often reported as outcome measures in surgery, were classified as grade I in 50%, grade IIa in 22%, grade IIb in 28%, grade III 0.3% and grade IV in 0.3% of cases. The results of this study show the need for a universal severity grading system for complications, which should be reported in both surgical practice and surgical literature to assess quality of care and interpret the results of clinical trials.
Chapter 3 addresses the consequences and severity grade of a specific subset of entries in our complication registry: medical error. It was shown that the recorded incidence of errors in a cohort of 12121 patients was 6.1% (873 errors in 735 patients). Most errors were near misses indicating that they were without consequences for the patients. Of all recorded errors, 69.5 per cent had little or no consequences (grade I) and 25.2 per cent required therapeutic interventions (grade IIa and IIb). Errors resulted in permanent injury (grade III) in 4.7 per cent, and death of the patient (grade IV) in 0.6 per cent of patients. Thus, almost one third of the medical errors had either temporary or lasting consequences for the patients. The errors without consequences are in fact near misses. The common cause hypothesis states that near misses have similar causal pathways as adverse events which is an underlying assumption of many injury prevention programs.Since many near misses may happen without notice before a similar error with severe consequences occurs, we suggested that all errors should be registered and that these registries may be used for prevention of iatrogenic injury and quality improvement programs.
In *Chapter 4* we describe a prospective cohort study that was performed to evaluate the impact of complications on QoL in colorectal surgery. A second aim of this study was to evaluate the Clavien-Dindo complication classification (CDCC) by assessing the relationship between CDCC grade and postoperative QoL. Patients undergoing

colorectal surgery were evaluated prospectively over one year using the WHOQOL-Bref questionnaire. Patient data was prospectively recorded and complications were classified using the CDCC. Postoperative QoL in patients with minor and severe complications was compared to QoL in patients without complications using a general linear model. The relationships between CDCC and QoL were examined using correlations and multivariate regression. Of 218 patients, 130 (59.6%) had complications. In patients with severe complications there was a greater decrease in overall QoL, QoL-physical domain and QoL-psychological domain in the first six postoperative weeks, whereas patients with minor complications had QoL scores comparable to patients without complications. Interestingly, in all groups QoL returned to preoperative levels after one year. Change in QoL at six weeks significantly correlated with CDCC grade, especially in the physical domain (spearman's rho -0.29). Presence of severe complications was an independent predictor of Overall QoL, QoL-physical domain and QoL-psychological domain at six weeks. Severe complications are associated with reduced postoperative QoL. CDCC grade negatively correlates with change in QoL in the early postoperative period. The findings of this study support the theoretical framework of the Clavien-Dindo complication classification system.

In *Chapter 5* we prospectively investigated the impact of complications on health status, anxiety and depressive symptoms in a cohort of patients undergoing colorectal surgery. At present, little is known about the psychological impact of complications in colorectal surgery. Patients undergoing colorectal surgery were evaluated prospectively during one year using the CES-D, STAI and SF-36 questionnaires. Patient data and complications were prospectively recorded. Postoperative CES-D, STAI and SF-36 scores in patients with minor and severe complications were compared to scores of patients without complications using a general linear model. Of 218 patients, 130 (59.6%) had complications. Colorectal surgery significantly increased depressive symptoms and anxiety levels and lowered all domains of health status in all patient subgroups. Depressive symptoms and anxiety levels were not increased in patients with complications as compared to patients without complications. Patients with severe complications had a larger postoperative decrease in health status, most notably at six weeks postoperatively with the largest effects in the physical-, mental-, social- and vitality domains. Thus, severe complications cause a decrease in health status, but no increase in anxiety or depressive symptoms.

In *Chapter 6* we retrospectively investigated whether patients with pertrochanteric fractures treated outside working hours had a higher rate of complications and mortality than patients operated during regular working hours.During the study period 165 patients were operated during duty hours (DH) and 123 patients were operated during regular working hours (WH). There were no differences in early complications (DH 33% *versus* WH 33%) or total complications during follow-up (DH 40% *versus* WH 41%). Both in-hospital mortality (DH 12% *versus* WH 11%) and mortality after 1 year (DH 29% *versus* WH 27%) were comparable. Adjustment for possible confounders by multivariate logistic regression analysis revealed no increased risk of complications when patients were operated in duty hours. On the basis of these data, there is no medical reason to postpone operative reduction and fixation in patients

with a proximal femoral fracture to regular working hours.
In *Chapter 7* we describe a retrospective cohort study to investigate whether current practice where residents perform appendectomies affects quality of care. Appendicitis is among the most frequent conditions requiring urgent surgery. Admittance and surgery are often managed by residents. Therefore, we investigated whether there was a difference in incidence of complications and mortality in appendectomies performed by surgeons (S), supervised residents (SR), or unsupervised residents (UR). All patients undergoing appendectomy in our hospital between January 1, 2000, and December 31, 2009, were included in the analysis. Patients undergoing appendectomy by surgeons, supervised residents, and unsupervised residents were compared. Primary endpoints were complications and mortality.During the study period, 1538 patients were operated. The risk of complications (S: 20% vs SR: 17% vs UR: 16%) and mortality (S: 0.3% vs SR: 0.2% vs UR: 0.4%) were similar in all groups. In the multivariate model, the risk of complications in the group operated by supervised residents and unsupervised residents was similar to the risk of complications in patients operated by surgeons. Current practice where residents perform appendectomies either unsupervised or supervised by an experienced surgeon is safe and does not lead to more complications or negatively affect quality of care.

Future implications

Measuring the quality of care is important, for quality control and improvement, transparency and comparison between health care providers. Unfortunately, it has also proven to be very difficult. This thesis focussed on the use of complications for outcome measurement. Historically, complications have been used as outcome measures, and complication registries are now used in most hospitals in the Netherlands. Although they are a valuable part of quality measurement, the use of complication registries alone is insufficient. Complication registries only reflect a specific part of outcome. A high incidence of complications may indicate that substandard quality of care is delivered. However, the absence of complications, does not necessarily indicate good quality of care. For example, in colonic cancer, a low incidence of anastomotic leak or wound infections, does not imply that good oncological results are achieved. The incidence of complications, is only one of several outcome measures which should be used as complementary to other variables. In the Netherlands, several initiatives by different stakeholders are employed.
In 2015, there are now several organisations involved in the monitoring and measurement of quality of care. A single coordinating center appears to be lacking. The Health Care Inspectorate (Inspectie voor de Gezondheidszorg, IGZ) uses a set of clinical indicators to monitor quality of care[1]. It consists of structure-, process- and outcome measures. Hospitals are required by law to provide the information every year. The Dutch Health care insurance Board (College voor Zorgverzekeringen, CVZ) requires hospitals to provide data on 42 diagnosis groups[2]. The data is used for quality control and in the

future is expected to be used by patients to make an informed choice for a health care provider. A more recent and promising initiative is set up by the Dutch Institute for clinical auditing (DICA). It has developed a system to evaluate and improve quality of care in several surgical subspecialties. The data collected includes detailed baseline patient characteristics (including disease characteristics), operative details as well as outcome parameters, including complications. With regard to the Dutch Surgical Colorectal Audit, all hospitals participated and 97% of eligible patients were included in the registry[3]. The DICA registry at present probably is the best outcome registry although it lacks long term outcome data such as cancer recurrence rates and survival. In the future therefore, also long term outcome should be included in these registries.
Although the aforementioned programs all contribute to the monitoring of quality of care and have their use and value, there is need for an integrated outcome measurement system that covers the most frequent diagnosis groups in surgery. With several stakeholders (health care professionals, patients, government, health insurance organisations) using various different outcome registries and different parameters, both patients as well as health care providers cannot easily use the available information to assess the quality of care. Both short term outcome (perioperative mortality, complications including severity grade, failure to rescue) and long term outcome (survival, disease recurrence, patient reported outcome measures) should be assessed. The DICA registries at present seem to most closely resemble such a system and may be used as the blueprint for such as system.
Almost all outcome measures require significant effort to measure, as shown by the effort put in data collection by every hospital participating in the DICA registries. At present most quality assessment is done by health care professionals themselves. For some registries, the data is provided by the professionals and processed and presented by an independent organization, whereas in other registries the complete process is done by health care professionals alone. In the first case, independence and reliability of the data are better than in the second case, or at least are perceived by other stakeholders as more reliable and thrustworthy. Quality measurement and registries should be an integral part of the health care system and sufficient resources should be allocated for quality assessment. Ideally, there should be an independent organisation (either nationwide, regional or local) involved in the assessment of quality of care for a broad range of common pathologies. The health care insurance companies may contribute to these institutes for quality control. The health care providers should be informed of their performance on a regular basis to effectively use the data in feedback loops, for quality control and improvement.
We have come a long way since surgeons first started to register their complications, but to adequately assess the quality of care, we still have a long, long way to go.

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Eelke Bosma

Curriculum Vitae

Eelke Bosma werd op 18 mei 1977 geboren in het Rooms Katholiek Ziekenhuis te Groningen. Hij groeide op in Haren en Glimmen met zijn oudere zus Barbera en jongere broer Willem. In 1995 deed hij zijn VWO examen aan Augustinus College te Groningen. Hoewel hij eerst geen dokter wilde worden, zag hij het licht tijdens een ontwikkelingsproject in Bolivia en besloot hij zich toch in te schrijven voor de studie geneeskunde. Omdat hij de eerste keer werd uitgeloot startte hij in 1995 met psychologie, waar hij Mariska Top ontmoette, welke later zijn vrouw en moeder van drie kinderen zou worden. In 2015 strandde dit huwelijk. In 1996 werd hij alsnog ingeloot voor de studie geneeskunde. Hij behaalde het doctoraal examen in 2001 en het artsexamen in 2002. Na eerst een jaar op de spoedeisende hulp van het Jeroen Bosch ziekenhuis in Den Bosch gewerkt te hebben begon hij in 2003 als AGNIO in het St. Elisabeth ziekenhuis te Tilburg, alwaar hij in 2004 met de opleiding tot chirurg kon beginnen. Tijdens het perifere deel van zijn opleiding waren zijn opleiders prof. dr. J.F. Hamming, prof. dr. C.J.H.M. van Laarhoven, prof. dr. J.A.Roukema en dr. F. van der Heijden. Het vijfde jaar van de opleiding werd in het UMC St. Radboud gedaan met als opleider prof. dr. R.P. Bleichrodt. Na de opleiding tot chirurg werd hij chirurg in vervolgopleiding (CHIVO) tot Traumachirurg in het UMC Groningen, met als opleiders prof. dr. H. J. ten Duis en dr. K. W. Wendt. Sinds 1 februari 2012 is hij lid van de Chirurgen Maatschap Groningen in het Martini Ziekenhuis in Groningen. Eelke heeft 3 kinderen: Jente (9), Hielke (8) en Job (6). Zijn vrije tijd besteed Eelke graag aan het maken van muziek, onder andere op zijn Schotse en zijn Ierse doedelzak.